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105 CMR	**700.000**	**Implementation of M.G.L. c. 94C**
	701.000	**Regulations Adopted Jointly by the Department of Public Health & the Board of Registration of Pharmacy for the Implementation of M.G.L. c. 94C**
	702.000 - 720.000	**Reserved**
	721.000	**Standards for Approved Prescription Forms in Massachusetts**
	722.000	**Dispensing procedures for Pharmacists**
	723.000	**Reserved**
	724.000	**Implementation of M.G.L. c. 94D, the Controlled Substances Therapeutic Research Act**
	725.000 - 729.000	**Reserved**
	730.000	**Distribution of Biological Products**
	731.000	**Sale of Surplus biological Products**
	732.00 - 749.000	**Reserved**
	750.000	**Licensing & Approval of Drug Treatment Programs**
	751.000 - 799.000	**Reserved**
	800.000	**Required Requests for Anatomical Donations**
	801.000 - 899.000	**Reserved**

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9/29/2000

A true copy attest:

William Francis Galvin

WILLIAM FRANCIS GALVIN
Secretary of the Commonwealth

105 CMR 700.000: IMPLEMENTATION OF M.G.L. c. 94C

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700.001: Definitions

For the purpose of 105 CMR 700.000, the following definitions apply, in addition to those definitions appearing in M.G.L. c. 94C, § 1, unless the context or subject matter requires a different meaning.

Administer means the direct application of a controlled substance whether by injection, inhalation, ingestion or any other means to the body of a patient or research subject by:

(1) A practitioner or

(2) A registered nurse or licensed practical nurse at the direction of a practitioner in the course of his professional practice, or

(3) An ultimate user or research subject at the direction of a practitioner in the course of his professional practice.

Agent means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser; except that such term does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

ALS Attendant means a person employed by an ambulance service licensed to provide Advanced Life Support services in accordance with 105 CMR 170.502, or a person employed by a hospital which provides non-transport pre-hospital Advanced Life Support services, who has met the training requirements of 105 CMR 170.820:*EMT-Intermediate* or 105 CMR 170.840: *EMT-Paramedic* and is certified by the Department in accordance with 105 CMR 170.910. The term ALS attendant shall also include a person who has met the training requirements of 105 CMR 170.810: *EMT-Basic* and is certified according to 105 CMR 170.910, or who is currently certified by another state as an EMT, who is enrolled as a student in a training program at the Intermediate or Paramedic level which has been approved by the Department in accordance with 105 CMR 170.960 and when participating in that training program.

Bureau means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice or its successor agency.

Certified Nurse Midwife means a nurse authorized to practice as a nurse midwife by the Board of Registration in Nursing, as provided for in M.G.L. c. 112, §§ 80B and 80C and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq.*, most specifically 244 CMR 4.11 through 4.27.

Chemical Analyst means a person engaged in the qualitative or quantitative analysis of controlled substances within a scientific laboratory.

Chronic Patient means, for the purposes of 105 CMR 700.000 only, a person diagnosed by a physician as having a physical or mental illness characterized by slow progress and long continuance.

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Commissioner means the Commissioner of Public Health or his duly authorized agent.

Community Program means any community residential or day program serving mentally ill or mentally retarded persons which is funded, operated or licensed by the Massachusetts Department of Mental Health or Department of Mental Retardation, with the exception of programs funded under Title XIX of the Social Security Act.

Controlled substance means a drug, substance, or immediate precursor in any schedule or class referred to in M.G.L. c. 94C or 105 CMR 700.000.

Compounding means in the definition of "Manufacture", compounding a controlled substance other than:

(1) By a practitioner or,
(2) By a pharmacist subject to a prescription.

Deliver means to transfer, whether by actual or constructive transfer, a controlled substance from one person to another, whether or not there is an agency relationship.

Dental Hygienist means a person registered by the Board of Registration in Dentistry pursuant to M.G.L. c. 112, § 51.

Department means the Department of Public Health.

Department of Mental Health means the Massachusetts Department of Mental Health.

Department of Mental Retardation means the Massachusetts Department of Mental Retardation.

Depressant or stimulant substance means:

(1) A drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or any derivative of barbituric acid which the United States Secretary of Health, Education and Welfare has by regulation designated as habit forming; or
(2) A drug which contains any quantity of amphetamine or any of its optical isomers; any salt of amphetamine or any salt of an optical isomer of amphetamine; or any substance which the United States Attorney General has by regulation designated as habit forming because of its stimulant effect on the central nervous system; or
(3) Lysergic acid diethylamide; or
(4) Any drug except marihuana which contains any quantity of a substance which the United States Attorney General has by regulation designated as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

Dispense means to deliver a controlled substance to an ultimate user or research subject or to the agent of an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery.

Distribute means to deliver other than by administering or dispensing a controlled substance.

Drug means:

(1) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary or any supplement to any of them:
(2) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals;
(3) Substances, other than food, intended to affect the structure or any function of the body of man and animals; or

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(4) Substances intended for use as a component of any article specified in 105 CMR 700.001(M)(1) through 700.001(M)(3), exclusive of devices or their components, parts or accessories.

Fluoride Program Monitor means a dental assistant, school teacher, school aide or school volunteer.

Health Facility means:

(1) A hospital, hospital pharmacy, long-term care facility, or clinic or institution for unwed mothers, infirmary maintained in a town, convalescent home, nursing home or charitable home for the aged, licensed or maintained by the Department; or

(2) A public medical institution as defined in M.G.L. c. 118E, § 2; or

(3) Any institution licensed or maintained by the Department of Mental Health; or

(4) Any hospital, long-term care facility or clinic maintained by the Commonwealth.

(5) Any ambulance service licensed by the Department to provide Advanced Life Support services.

Home Care Setting means any place where a person resides which is not licensed or funded by the Commonwealth to provide institutional care or custody. Home care settings include, but are not limited to the following:

(1) an individual's private home;

(2) community residences or group homes licensed or funded by an agency of the commonwealth;

(3) shelters and day centers for the homeless; and

(4) hospice settings which are approved by the Department and which are not licensed to provide acute care or operated by a hospital so licensed.

Hospital means any institution, however named, whether conducted for charity or for profit, which is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis, medical, surgical or restorative treatment which is rendered within said institution.

Immediate Precursor means a substance which the Commissioner has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

Implantable Infusion Pump means a device that is intended to be implanted in the human body for the purpose of delivering a controlled flow of drug(s).

Institutionalization means admission on an inpatient basis to in one of the following settings:

(1) long-term care facilities, as that term is defined in 105 CMR 700.000;

(2) hospitals, as that term is defined in 105 CMR 700.000.

Isomer means the optical isomer, except that wherever appropriate it shall mean the optical, position or geometric isomer.

Labeling means in the definition of "manufacture", labeling or relabeling other than:

(1) By a practitioner, or

(2) By a pharmacist.

Long-Term Care Facility means any institution whether conducted for charity or profit, which is advertised, announced or maintained for the express or implied purpose of providing three or more individuals admitted thereto with long-term resident, nursing, convalescent or rehabilitative care; supervision and care incident to old age for ambulatory persons; or retirement home care for elderly persons. For the purposes of 105 CMR 700.000 only, long-term care facility shall include hospitals which are licensed solely to provide chronic and/or rehabilitative care, state schools for mentally retarded persons, state hospitals for mentally ill persons, convalescent or nursing homes, rest homes, infirmaries maintained in towns and charitable homes for the aged.

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(1) "Convalescent or nursing homes, rest homes, infirmaries maintained in a town, and charitable homes for the aged" shall have the same meanings as those terms defined in M.G.L. c. 111, § 71.

(2) "Long-Term Care" means care of significant duration, as distinguished from acute short-term care provided in a general hospital, and shall not include care provided in a hospital licensed to provide acute care.

Manufacture means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, including any packaging or repackaging of the substance or labeling or relabeling of its container except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging or labeling of a controlled substance:

(1) By a practitioner as an incident to his administering a controlled substance in the course of his professional practice, or

(2) By a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

Marihuana means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; and resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil or cake of the sterilized seed of the plant which is incapable of germination.

Medication Order means a written order for medication entered on a patient's medical record maintained at a hospital or other inpatient health facility and is dispensed for immediate administration to the ultimate user by an individual authorized by M.G.L. c. 94C to administer such medication.

Narcotic drug means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(2) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in 105 CMR 700.001(T)(1), but not including the isoquinoline alkaloids of opium;

(3) Opium poppy and poppy straw;

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

National Association of Boards of Pharmacy (NABP) Number means a unique seven digit number issued by the National Council for Prescription Drug Programs (NCPDP).

National Drug Code Number (NDC) means a nationally recognized standard which identifies drug products using a unique number, issued by the United States Food and Drug Administration, involving three components. The first component identifies the drug manufacturer ("LABELER NO.") the second identifies the product "PRODUCT NO.", the third identifies the package size "PKG".

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Non-self-medicating means personally taking or applying prescription medication in the manner directed by the prescribing practitioner, with more than minimal assistance or direction by the program staff, as determined in accordance with procedures and criteria established by the Department of Mental Health or Department of Mental Retardation and approved by the Department of Public Health.

Nurse Practitioner means a nurse authorized to practice as a nurse practitioner by the Board of Registration in Nursing as provided for in M.G.L. c. 112, § 80B and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq.*, most specifically 244 CMR 4.11 through 4.27.

Opiate means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under M.G.L. c. 94C, § 2, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts, dextromethorphan. It does include its racemic and levorotatory forms.

Opium Poppy means the plant of the species Papaver somniferum L., except its seeds.

Oral Prescription means an oral order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse, or practical nurse.

Packaging means in the definition of "manufacture", packaging or repackaging a controlled substance other than:

(1) By a practitioner or,

(2) By a pharmacist.

Patient Identifier means a positive identification of the person who is receiving the prescription for a drug in Schedule II from the pharmacy and consists of one of the following:

(1) a valid driver's license number;

(2) a valid military identification card number; or

(3) the number of a valid identification card issued pursuant to M.G.L. c. 90, § 8E or similar statute of another state or the federal government. In the case of a recipient less than 18 years of age with no such identification the patient identifier may be that of the recipient's parent or guardian. In the case of an animal, the patient identifier may be that of the owner.

Person means individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

Physician Assistant means a physician assistant authorized to practice by the Board of Registration of Physician Assistants, as provided for in accordance with M.G.L. c. 112, § 9I and authorized to prescribe by St. 1991, c. 445, § 7(g) in accordance with regulations of the Board of Registration of Physician Assistants, 263 CMR 2.00 *et seq.*

Poppy Straw means all parts, except the seeds of the opium poppy, after mowing.

Practical nurse means a nurse who is licensed pursuant to the provisions of M.G.L. c. 112, § 74A.

Practitioner means:

(1) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;

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(2) A pharmacy, hospital or other institution registered to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in the commonwealth.
(3) An optometrist authorized by M.G.L. c. 112, §§ 66 and 66B and registered pursuant to M.G.L. c. 94C, § 7(h) to utilize and prescribe topical therapeutic pharmaceutical agents, as defined in M.G.L. c. 112, § 66B, in the course of professional practice in the commonwealth.

Pre-Hospital ALS Service means an ambulance services licensed to provide Advanced Life Support in accordance with 105 CMR 170.502 or a hospital unit which provides non-transport pre-hospital Advanced Life Support services.

Private School means the board of trustees, board of directors or comparable board responsible for operating a private elementary or secondary school program.

Prescription drug means any and all drugs upon which the manufacturer or distributor has, in compliance with federal laws and regulations, placed the following: "Caution, Federal law prohibits dispensing without prescription."

Psychiatric Nurse means a nurse authorized to practice as a psychiatric nurse mental health clinical specialist by the Board of Registration in Nursing, as provided for in M.G.L. c. 112, § 80B and regulations of the Board of Registration in Nursing, 244 CMR 4.00 *et seq.*, most specifically 244 CMR 4.11 through 4.27.

Registered Individual Practitioner shall mean a physician, dentist, veterinarian, podiatrist, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant who is registered pursuant to 105 CMR 700.004.

Registered Nurse means a nurse who is registered pursuant to the provisions of M.G.L. c. 112, § 74.

Registrant means a person who is registered pursuant to any provision of M.G.L. c. 94C.

Registration means unless the context specifically indicates otherwise such registration as is required and permitted only pursuant to the provisions of M.G.L. c. 94C.

Registration number means the unique registration number required with respect to a practitioner by, and assigned to a practitioner by, the Bureau of Narcotics and Dangerous Drugs or by the Department of Public Health or both.

Researcher means a person who engages in or conducts research involving substances, whether controlled or not, which are being used or are to be used on humans.

Sample Medication for the purpose of 105 CMR 700.000 shall mean a unit of prescription drug distributed by the manufacturer or distributor to practitioners in the original package from the manufacturer, not repackaged and given free of charge to patients. Such medications shall include but not be limited to those medications dispensed as part of an indigent patient drug program.

Schedule means the list of controlled substances established by the Commissioner pursuant to the provisions of M.G.L. c. 94C, § 2 for purposes of administration and regulation.

School means a public or private elementary or secondary school, or day care center or group care facility licensed by the Office for Children in accordance with M.G.L. c. 28A, § 10.

School District means the local educational agency, which includes the school committee, board of trustees, educational collaborative board, or other public entity responsible for operating a public elementary or secondary school program.

Scientific Laboratory means a facility maintained primarily for the analysis or examination of controlled substances or their precursors, and which is not a facility or part of a facility otherwise registered to manufacture, distribute, dispense or possess controlled substances.

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Self-medicating means personally taking or applying prescription medication in the manner directed by the prescribing practitioner, with no more than minimal assistance or direction from program staff, in accordance with procedures and criteria established by the Department of Mental Health or Department of Mental Retardation and approved by the Department of Public Health.

Supervising Physician means a physician who provides supervision to a physician assistant in accordance with M.G.L. c. 112, §§ 9C through 9H, or who provides supervision to a certified nurse midwife, a nurse practitioner or psychiatric nurse mental health clinical specialist as provided for in 244 CMR 4.05(9) (Board of Registration in Nursing).

Teacher means a person who conducts teaching activities using controlled substances in a teaching institution accredited by the Commission on Institutions of Higher Education.

Tetrahydrocannabinol means tetrahydrocannabinol or preparations containing tetrahydrocannabinol excluding marihuana except when it has been established that the concentration of delta-9 tetrahydocannabinol in said marihuana exceeds 2½%.

Ultimate user means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

Universal Claim Form (UCF) means a nationally recognized standard form developed by the National Council for Prescription Drug Programs, used for billing prescription drug claims to insurance plans and available through the pharmacy's local wholesaler.

Written prescription means a written order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse or practical nurse.

700.002: Schedules of Controlled Substances

The following schedules of controlled substances are established:

(A) Schedule I. Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 Code of Federal Regulations (CFR) 1308.11, as most recently amended.

(B) Schedule II. Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.12, as most recently amended.

(C) Schedule III. Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.13, as most recently amended.

(D) Schedule IV. Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.14, as most recently amended.

(E) Schedule V. Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.15, as most recently amended.

(F) Schedule VI. Schedule VI shall consist of all prescription drugs, which are not included in any other schedule established by the Commissioner.

700.003: Registration of Persons for a Specific Activity or Activities In Accordance With M.G.L. c. 94C, § 7(g)

(A) An ALS attendant may administer controlled substances including intravenous solutions in the performance of attendant duties provided that:

(1) the ALS Service for which he/she serves is registered with the Department's Division of Food and Drugs in accordance with 105 CMR 700.004; and

(2) the ALS Service maintains a current listing of names of attendants employed by the Service who may administer medications;

(3) the administration follows written treatment protocols established in accordance with 105 CMR 170.000 *et seq*;

(4) the attendant performs those functions for which he/she is trained in accordance with 105 CMR 170.000 *et seq*.

(B) Dental hygienists and fluoride program monitors employed by or affiliated with a registered school may administer fluoride tablets or fluoride mouthrinse to school children aged three through 18 provided that:

(1) The school has registered with the Department by sending a letter of intent to administer fluoride treatments to the Division of Dental Health and by providing whatever further information the Commissioner may require; and

(2) The child's parent or guardian has been informed in writing of the nature, dose and effects of fluoride tablets and mouthrinse, and has consented in writing to the administration of fluoride tablets or mouthrinse on behalf of the child; and

(3) The tablets or mouthrinse is administered in accordance with the order of a physician or dentist employed by or associated with a local Board of Health or school; and

(4) The fluoride program monitor has been trained to administer and store fluoride tablets and mouthrinse in accordance with a training program designed by the Commissioner; and

(5) All fluoride mouthrinse and tablets possessed by the registered school are stored securely under lock and key; and

(6) The registered school maintains such records and files such reports concerning the fluroide program as the Commissioner may require.

(C) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may issue written prescriptions and medication orders for Schedule II through VI controlled substances, provided that the following requirements are met:

(1) The certified nurse midwife, nurse practitioner and psychiatric nurse meets all requirements set forth in regulations established by the Board of Registration in Nursing, 244 CMR 4.00 *et seq*. and M.G.L. c. 112, § 80B, 80C, 80E, and 80F.

(2) The physician assistant meets all requirements set forth in regulations established by the Board of Registration of Physician Assistants, 263 CMR 2.00 *et seq*. and M.G.L. c. 13, § 10B and M.G.L. c. 112, §§ 9C through 9K.

(3) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant registers with the Department's Division of Food and Drugs, in accordance with 105 CMR 700.004 and with the Drug Enforcement Administration, in accordance with 21 CFR 1300.

(4) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant practices in accordance with written guidelines governing the prescription of medication mutually developed and agreed upon by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant and a supervising physician pursuant to regulations promulgated under M.G.L. c. 112, §§ 80B, 80C, 80E and 80G and M.G.L. c. 112, § 9E that describes the methods to be followed in managing a health care situation or in resolving a health care problem. 105 CMR 700.03(C)(4)(a) and (b) will remain in full force and effect until such time as regulations are promulgated by the Board of Registration in Nursing in accordance with M.G.L. c. 112, §§ 80B, 80C, 80E and 80G and by the Board of Registration of Physician Assistants in accordance with M.G.L. c. 112, § 9E.

700.003: continued

(a) Such guidelines for the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall address, but need not be limited to, such issues as frequency of medication review by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant and the supervising physician; review of initial prescriptions or changes in medication by the supervising physician; procedures for initiating intravenous solutions; and limits, if any, on the types of medication to be prescribed, the quantity and duration of prescriptions and the issuance of refill prescriptions.

(b) In the case of a Schedule II drug as defined in 105 CMR 700.002, a prescription shall be reviewed by a supervising physician within 72 hours of issuance.

(5) All prescriptions issued by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant are consistent with the scope of practice as defined by 244 CMR 4.26 for nurses practicing in the expanded role and 263 CMR 2.00 for physician assistants.

(6) The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may order controlled substances in Schedule VI from a drug wholesaler, manufacturer, laboratory or distributor. For the purpose of dispensing medication in Schedules II-V for immediate treatment, the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may obtain such medication only as supplied by the supervising physician or obtained through a written prescription for the patient.

(7) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may issue oral prescriptions in accordance with M.G.L. c. 94C, § 20, provided that the person issuing the prescription clearly identifies his or her name and professional designation to the pharmacist and provides his or her registration number, work address, phone number, and the name of the supervising physician. An oral prescription shall be followed up with a written prescription by the certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant to be provided to the pharmacist or postmarked within a period of not more than seven days or such shorter period as required by federal law, in accordance with M.G.L. c. 94C, § 20.

(8) A certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant may prescribe controlled substances for a patient in a health facility or other setting through use of written medication orders entered on the patient's medical record maintained at the facility, provided that such written orders meet all applicable provisions of 105 CMR 700.000 and all applicable state and federal regulations for the licensure of these facilities.

(D) An Emergency Medical Technician (EMT), performing patient care duties as an ambulance operator or attendant or as a member of a first responder service may administer those controlled substances in Schedule VI approved by the Department for administration by EMT-Basics, provided that:

(1) such administration is in accordance with 105 CMR 170.810(F); and

(2) the ambulance or first responder service that employs the EMT is registered in accordance with 105 CMR 700.004.

(E) A school district or private school may register solely for the purpose of permitting trained school personnel to administer controlled substances in accordance with 105 CMR 210.000.

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(F) Employees of community programs may administer or assist in the administration of prescription medications to non-self-medicating persons, provided that:

(1) Registration. The community program is registered with the department in accordance with 105 CMR 700.004, and meets the following requirements:

(a) Administration or assistance in the administration of prescription medication to non-self-medicating clients shall be carried out only by duly licensed professional staff or by unlicensed program staff of registered community programs who have successfully completed the training specified in 105 CMR 700.003(F)(2);

(b) The program shall establish, maintain, and operate in accordance with policies which ensure that medication is administered only by properly trained and certified personnel;

(c) The program shall maintain a current written listing of those staff members who have successfully completed a training program meeting the requirements of 105 CMR 700.003(F)(2);

(d) The Department of Public Health shall be permitted by the program to inspect program and clients' records pertaining to the use and administration of prescription medications and is permitted announced or unannounced on-site visits or inspections of common areas and such other inspections as the Department of Public Health is authorized to make in order to monitor the program's compliance with 105 CMR 700.000.

(e) The Division of Food and Drugs within the Department of Public Health shall promptly be notified by the program of any suspected shortages or diversion of prescription medication;

(f) The program shall document in the client's record any administration of prescription medication in a manner inconsistent with the practitioner's prescription or in violation of 105 CMR 700.000. The program shall also promptly report to the Department of Mental Health or Department of Mental Retardation, as appropriate, on a form approved jointly by the Department of Public Health and said Departments, any administration of prescription medication in a manner inconsistent with the practitioner's prescription or in violation of 105 CMR 700.000 which staff has reason to believe created a risk of harm to the client. Such form shall be provided, upon request, to the Department of Public Health;

(g) The program shall provide or arrange for technical assistance and advice to be provided as needed by a Registered Nurse, Registered Pharmacist, or other Licensed Practitioner when questions arise regarding appropriate administration practices or the effects of medications. The program shall establish policies and procedures which ensure reasonable access to such assistance and advice;

(h) The program, professional staff and program staff shall comply with all applicable requirements of M.G.L. c. 94C, the Controlled Substances Act, as well as 105 CMR 700.000 and all pertinent regulations of the Department of Mental Health or Department of Mental Retardation, including those pertaining to storage, labeling, administration and documentation of prescription medication, medical back-up, review of medication, and emergency procedures.

(2) Training. No unlicensed staff person may administer or assist in the administration of prescription medications without successfully completing a training program which meets the specifications for a training curriculum and examination process established jointly by the Department of Public Health and the Department of Mental Health and/or the Department of Mental Retardation, as well as the following requirements:

(a) The training program shall be taught by a registered nurse, nurse practitioner, physician assistant, pharmacist, or physician who meets applicable requirements for a trainer established jointly by the Department of Public Health and the Department of Mental Health and/or the Department of Mental Retardation;

(b) The Department of Public Health and, as appropriate, the Departments of Mental Health and Mental Retardation shall have the authority to monitor the training program for compliance with established standards;

(c) The training program shall keep records of all persons who have successfully completed the training program which shall be made available to the Department of Public Health and, as appropriate, to the Departments of Mental Health and Mental Retardation upon request;

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(d) Each person who successfully completes the training shall be certified by the Department of Mental Health or the Department of Mental Retardation, as appropriate, and shall be provided with such documentation of completion of the training as approved by the Department of Mental Health and/or the Department of Mental Retardation. The original documentation of completion shall be provided to and maintained by the program;

(e) No person may continue to administer or assist in the administration of prescription medication beyond two years from the completion of the initial training unless such person has met standards for retraining and/or retesting established by the Department of Mental Health and/or the Department of Mental Retardation and approved by the Department of Public Health.

(3) Storage. The program meets all applicable Department of Mental Health or Department of Mental Retardation regulations as to storage and handling of prescription medications as well as the following requirements:

(a) All prescription medications which are consumed by clients who are non-self-medicating shall be kept in a locked container or area. The program shall have a written policy on which persons may have access to such container or area, how access to the key, combination and/or container or area is to be restricted, and under what conditions authorized persons may have access to the container or area;

(b) Prescription medications for clients who are self-medicating shall be stored in a locked container or area unless the program director makes a determination that unlocked storage of the prescription medication poses no threat to the health or safety of the client or other clients; provided, however, that all narcotics, tranquilizers and barbiturates shall be stored in a locked container or area;

(c) Outdated prescription medications and prescription medications which have not been administered due to a change in the prescription or a stop order shall be disposed of and the disposal documented in accordance with policies established by the program, provided that disposal occurs in the presence of at least two witnesses and in accordance with any policies of the Department of Public Health:

(4) Labeling. All medications are properly labeled in accordance with M.G.L. c. 94C, § 21 and the following requirements:

(a) Program staff shall not repack or relabel prescription medications which are taken or applied at any location or program regularly or frequently attended by the client. All such prescription medications shall be packed and labeled by a pharmacist or, in the case of prescription medication dispensed for immediate treatment, by the dispensing practitioner;

(b) Where prescription medication is consumed by a client at two or more locations on a regular or frequent basis, the prescription medication shall be stored in a separate, properly packaged and labeled medication container at each location. In circumstances where this is not practical or feasible, the Department of Mental Health and/or Department of Mental Retardation shall establish an alternative procedure approved by the Department of Public Health to be used.

(c) The program shall have policies for obtaining a properly labeled container where there is a change in prescription or where the client frequently or regularly receives prescription medication in two or more locations.

(5) Administration. All prescription medications are administered in accordance with M.G.L. c. 94C, applicable regulations for the Department of Mental Health or the Department of Mental Retardation and the following requirements:

(a) All prescription medications shall be administered in accordance with the prescription of a practitioner;

(b) Prescribed medications shall only be administered to or taken by the person for whom the prescription has been written;

(c) The program shall have a policy which specifies the administrative procedures to be followed when there is a medical emergency relating to medication. Such policy shall include a list of staff persons and medical personnel to be contacted which is up to date, readily available to staff and clearly indicates who is to be contacted on a 24 hour a day, seven day a week basis. The medical personnel to be contacted shall include the prescribing practitioner or, if unavailable, another licensed practitioner or appropriate emergency room personnel;

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(d) Certified staff employed by programs registered with the Department may only administer prescription medications which are oral, topical, ophthalmic, otic, internasal, suppository, or products which are administered by inhalation;

(e) Parenteral drugs generally intended for self administration, or drugs administered by gastric tube may be administered by staff members who have successfully completed a specialized training program in such technique taught by a physician, physician assistant, pharmacist, registered nurse, or nurse practitioner, approved by the Department of Public Health and/or the Departments of Mental Health or Mental Retardation. Such technique shall be used only with the written authorization and in accordance with the written instructions of the prescribing physician;

(f) Whenever possible, a prescription for medication shall be limited to a 30 day supply and one refill. The prescribing practitioner shall be notified by program staff of this requirement;

(g) Where a client who is non-self-medicating receives prescription medication at a location other than a program site covered by 105 CMR 700.000 (off-site), the program whenever possible shall identify an individual responsible for administering the medication and make available to that person instructions as to how the medication is to be administered;

(h) An over-the-counter drug may be consumed or applied by a non-self medicating client who is already receiving prescription medication only (i) with the prior approval of a practitioner; or (ii) after consultation with a pharmacist or registered nurse; or (iii) in accordance with applicable guidelines established by the Department of Mental Health and/or the Department of Mental Retardation, with the approval of the Department of Public Health.

(6) Documentation. All prescriptions and administration of prescription medications shall be documented in accordance with applicable regulations of the Department of Mental Health or Department of Mental Retardation and the following requirements:

(a) All prescriptions for medication shall be noted in the client's record on medication and treatment forms developed by the Department of Mental Health and/or the Department of Mental Retardation and approved by the Department of Public Health. Such forms shall specify for each client the name and dosage of medication, the indication for which the medication is prescribed, and contraindications or possible allergic reactions, possible side effects and appropriate staff response, and special instructions, including steps to be taken if a dose is missed. The program shall establish appropriate policy and procedures to address how program staff shall obtain relevant prescription information in accordance with the requirements of 105 CMR 700.003(F)(6). In addition, such policy and procedures shall ensure that telephone medication orders and/or medication changes are received from licensed practitioners and properly documented in the client's record;

(b) The program shall ensure that staff have ready access to such information as listed in 105 CMR 700.003(F)(6)(a), by maintaining on site either an appropriate reference approved by the Department of Public Health or, for each drug administered, a copy of the pertinent section of such reference or a medication-specific drug information sheet which states in plain language generally why the drug is used, when it is to be administered, how it should be administered, any special instructions or precautions, proper storage conditions, possible side effects and what is to be done if a dose is missed;

(c) The taking or applying of medications for non-self-medicating clients, including over the counter drugs, shall be documented in the client's medication and treatment forms; (i) the time that the medication is taken or applied shall be noted in the record; (ii) the record shall indicate any off-site taking or applying of medication by a non-self-medicating client which would normally occur at the program site; (iii) clients who are self-medicating shall not be required to document their own self-administration of medication;

(d) Any change in medications or dosage levels of a medication shall be treated as a new medication order for the purposes of documentation;

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(e) A non-self-medicating client's residential program shall notify the client's day program of any prescription medications which the client is taking and shall provide the program with a copy of the medication and treatment forms meeting the requirements of 105 CMR 700.003(F)(6)(a) for each prescription medication which the client receives. Where a non-self-medicating client receives prescription medication solely at the day program, the day program shall have responsibility for notifying the residential program and providing it with a copy of the medication and treatment forms;

(f) The program shall establish procedures to document the date that any client's prescription is filled and the quantity of medication dispensed by the pharmacy;

(g) Except for persons who are self-medicating, the program shall maintain a documented accounting of the quantities of all controlled substance in schedule's II-V, stored by the program, which shall be reconciled at the end of each shift or as otherwise approved by the Department.

(G) Optometrists may utilize and issue written prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 112, §§ 66 and 66B, for those topical pharmaceutical agents in Schedule VI required for the diagnosis, prevention, management or treatment of abnormal ocular conditions or diseases as defined in M.G.L. c. 112, § 66, except glaucoma.

700.004: Registration Requirements

(A) Persons Required to Register. Every person who is required to be registered with the Commissioner under M.G.L. c. 94C shall register with said Commissioner as hereafter provided:

(1) Every person other than a registered retail drug business or wholesale druggist shall register if he:

(a) Manufactures, distributes, or dispenses any controlled substance, or

(b) Uses any controlled substance in research, teaching, or chemical analysis, or

(c) Possesses controlled substances with the intent to manufacture, distribute, or dispense any such substance, or

(d) Possesses controlled substances with the intent to conduct research, teaching or chemical analysis using any such substance.

(2) Persons required to be registered for controlled substances shall register separately for each one of the following business or professional activities applicable to him.

(a) Chemical Analyst
(b) Community Program
(c) Dentist
(d) Health Facility
(e) Manufacturer
(f) Physician
(g) Podiatrist
(h) Researcher
(i) Scientific Laboratory
(j) Teacher
(k) Veterinarian
(l) Ambulance Service/First Responder Service
(m) School
(n) Physician Assistant
(o) Nurse Practitioner
(p) Certified Nurse Midwife
(q) Psychiatric Nurse
(r) School District
(s) Private School
(t) Optometrist

(3) A person involved in the qualitative or quantitative analysis of controlled substances within a scientific laboratory is required to register as an individual chemical analyst; in addition to the requirement that the scientific laboratory is also required to register.

(4) A hospital or other health facility is required to register if:

(a) It is not registered with the Board of Registration in Pharmacy and

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(b) It possesses controlled substances which are safeguarded for or intended to be dispensed to any patient.

(5) A teacher in a teaching institution using controlled substances for instructional purposes is required to register, but the teaching institution is not required to register for teaching purposes.

(B) Exemptions from Requirement to Register. Persons primarily responsible for activities involving controlled substances in Massachusetts are required to register.

(1) Owners, partners and stockholders and parent corporations of registered businesses are exempted with regard to such ownership activities from the requirement to register.

(2) Persons exempted from the requirement to register by M.G.L. c. 94C are:

(a) An agent or employee of a registered manufacturer, distributor or dispenser acting in the usual course of his business or employment;

(b) A common or contract carrier or warehouseman or his employee, acting in his usual course of business or employment;

(c) A public official or law enforcement officer acting in the regular performance of his official duties.

(d) An ultimate user or research subject, at the direction of a practitioner in the course of his professional practice;

(e) A registered nurse or licensed practical nurse acting under the direction or authorization of a practitioner in the course of their professional practices.

(3) Any student enrolled in a school for nurses or practical nurses duly approved in accordance with M.G.L. c. 112, is exempted from the requirement to register when:

(a) Performing nursing services incidental to any prescribed course in such school, and

(b) Authorized or directed by a physician, dentist, podiatrist, veterinarian, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant duly registered under 105 CMR 700.000.

(4) Certain persons engaged in interstate or foreign commerce are exempted from the requirement to register with respect to the exempted business activities only as follows:

(a) Vessels engaged in international trade or in trade between ocean ports of the United States.

(b) Aircraft operated by air carriers under a certificate or permit issued pursuant to the Federal Aviation Act of 1958.

(c) Persons who import controlled substances into the jurisdiction of the United States, and are in compliance with applicable Federal Law.

(d) Persons who export controlled substances from the jurisdiction of the United States, and are in compliance with applicable Federal law.

(5) An intern, fellow, medical officer, alien physician, registered nurse, licensed practical nurse, or other authorized person may dispense controlled substances under the registration of the hospital or other registered health facility by which he is employed and a "responsible person", as defined by the Department, may dispense controlled substances by ingestion only at the direction of a practitioner in the course of his professional practice, under the registration of the registered health facility by which such person is employed, in lieu of being registered himself provided that:

(a) He is authorized to dispense controlled substances in accordance with M.G.L. c. 112 if applicable, and

(b) Such dispensing is done in the usual course of his business or professional practice, and

(c) The hospital or other registered health facility by whom he is employed has verified with the appropriate Board of Registration, if applicable, that the person is permitted to dispense controlled substances within Massachusetts, and

(d) Such person is acting only within the scope of his employment in the hospital or other registered health facility, and

(e) The hospital or other registered health facility authorizes the person to dispense controlled substances under the registration number of the hospital or other registered health facility and designates a specific internal code to consist of a numeric suffix to the health facility registration number preceded by a hyphen for each such person so authorized, and

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(f) The hospital or other registered health facility maintains a current list of internal codes and makes such codes available at all times to other registrants, the Commissioner, and authorized law enforcement agencies.

(6) A registered pharmacist may dispense by administration influenza vaccine and other immunizations designated by the Department to persons 18 years of age or older provided that:

(a) Such registered pharmacist is authorized to dispense controlled substances in accordance with M.G.L. c. 112;

(b) Such administration is conducted pursuant to the order of a practitioner; and

(c) Such activity is conducted in accordance with guidelines adopted by the Department which shall include, but not be limited to, requirements for:

1. training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body; and
2. pre-administration education and screening;
3. vaccine storage and handling;
4. administration of medication, including administration of controlled substances as necessary for the management of medical emergencies;
5. record keeping; and
6. reporting of adverse events.

(C) Separate Registrations Required for Separate Activities. Each person shall obtain a separate registration for each group of activities in which he engages.

(1) A person engaged in one of the following business or professions shall be deemed to be registered only for the activities appropriate to that business or profession as follows:

(a) A person registered as a manufacturer is deemed to be
1. registered to manufacture controlled substances, and
2. registered to distribute controlled substances to registered persons.

(b) A person registered as a chemical analyst or scientific laboratory is deemed to be
1. registered to manufacture controlled substances, and
2. registered to conduct chemical analysis including quality control with respect to controlled substances, and
3. registered to distribute controlled substances to other registrants.

(c) A person registered as a teacher is deemed to be
1. registered to manufacture controlled substances, and
2. registered to conduct instructional activities with controlled substances.

(d) A registered physician, dentist, veterinarian, or podiatrist, registered by the appropriate Board of Registration is deemed to be registered to dispense controlled substances.

(e) A registered hospital, or other registered health facility is deemed to be registered to dispense controlled substances.

(f) A person registered as a researcher is deemed to be, within the scope of the protocol submitted to the Commissioner, if applicable,
1. registered to manufacture controlled substances, and
2. registered to distribute controlled substances to registered persons and
3. registered to conduct research with respect to controlled substances.

(g) A registered ALS Service is only registered to possess those controlled substances and instruments to administer controlled substances, in quantity and in kind, which are necessary for pre-hospital emergency medical care, and which are obtained from hospital pharmacy.

(h) A registered school is deemed to be registered solely in order to possess fluoride tablets and mouth rinse and to authorize fluoride program monitors and dental hygienists to administer fluoride tablets and mouth rinse in accordance with 105 CMR 700.000.

(i) A community program is registered for the sole purpose of authorizing its employees to administer or assist in the administration of controlled substances which are obtained from a pharmacy upon the prescription or order of a practitioner.

(2) No person shall engage in any activities involving any controlled substance in any schedule for which he is not registered.

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(D) Automatic Registrations. The Commissioner shall automatically issue a registration to dispense controlled substances other than for research pursuant to M.G.L. c. 94C, § 8, to any physician, dentist, podiatrist, or veterinarian who is duly authorized to practice his profession in the Commonwealth, provided that, any such physician, dentist, podiatrist, or veterinarian shall only be registered for Massachusetts Schedule VI and for the same schedules as he is registered with the Bureau of Narcotics and Dangerous Drugs.

(1) Any physician, dentist, podiatrist or veterinarian who is not registered with the Bureau of Narcotics and Dangerous Drugs shall be automatically registered to dispense controlled substances but only for Massachusetts Schedule VI.

(2) The Commissioner may periodically recall registrations to dispense controlled substances issued to practitioners, in accordance with M.G.L. c. 94C, § 7(f), and may issue a new registration upon verification that the practitioner continues to be duly authorized to practice his profession in Massachusetts.

(E) Time for Application and Term of Registration. No person required to be registered shall engage in any activity for which registration is required until he is registered for that activity.

(1) Any person who is registered with the Commissioner may apply to be re-registered on a form provided by the Commissioner not more than 60 days before the expiration date of his registration.

(2) Any registration issued by the Commissioner other than a registration to conduct research activities with Schedule I controlled substances or a registration to dispense automatically issued shall be effective for one year from the date of issuance.

(3) A registration issued to conduct research with Schedule I controlled substances shall be for such period, not to exceed one year, as may be specified by the Commissioner.

(4) Any person who is registered may at any time apply for a modification of his registration on a form supplied by the Commissioner.

(F) Separate Registrations Required for Separate Locations. A separate registration is required at each principal place of business or professional practice at one general physical location where the applicant or registrant manufactures, distributes or dispenses controlled substances, or uses controlled substances in research, teaching, or chemical analysis.

(1) The following locations are deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(a) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered.

(b) An office used by an agent of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances, nor serves as a distribution point for filling sales orders.

(c) An office or registered hospital or other registered health facility which is used by a physician, dentist, podiatrist, veterinarian, or optometrist who is registered at another location which is his principal place of professional practice, provided that no controlled substances are maintained by such practitioner at any place where he is not registered.

(G) Limitations on Registration for Schedule I. No person other than a person proposing to manufacture controlled substances in Schedule I; or a person proposing to conduct research on human beings involving controlled substances in Schedule I pursuant to M.G.L. c. 94C, § 8; or a person proposing to engage in qualitative or quantitative analysis of those controlled substances in Schedule I within a scientific laboratory shall be registered for activities involving the manufacture, distribution or dispensing of Schedule I controlled substances unless expressly authorized so to do by the Commissioner:

(1) Every applicant for registration for activities involving the manufacture, distribution or dispensing of controlled substances in Schedule I shall demonstrate to the satisfaction of the Commissioner, unless waived by the Commissioner:

(a) That he is registered by the Bureau of Narcotics and Dangerous Drugs specifically to manufacture, or conduct research involving, or to conduct chemical analysis with, controlled substances in Schedule I, and

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(b) That he has never had an application denied or suspended or revoked by the Bureau of Narcotics and Dangerous Drugs or any predecessor agency for violation of any law or regulation and

(c) That his physical security controls are specifically approved by the Bureau of Narcotics and Dangerous Drugs, and

(d) That in the case of an application to conduct research with controlled substances in Schedule I his protocol is attached to his application and satisfies the requirements of 105 CMR 700.009(H).

NON-TEXT PAGE

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(H) Content and Form of Application. Each application for registration, renewal of a registration, or modification of a registration shall be on a form provided or approved by the Commissioner.

(1) The application form shall include:

(a) The applicant's name;

(b) The name and title of a responsible authorized representative of the applicant if the applicant is an institution, corporation, or other entity;

(c) The applicant's principal place of carrying on his or its business or profession;

(d) The applicant's business or professional activity for which he proposes to be registered;

(e) The schedules for which the applicant wishes to be registered; and

(f) The applicant's Bureau of Narcotics and Dangerous Drugs registration number, if any.

(g) The application of a certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall include the name and address of a supervising physician, a general description of the supervising physician's scope of practice, and the signature of the supervising physician. The certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall promptly notify the Department of any termination of employment, change of address, or change of supervising physician.

(2) The Commissioner may, in his judgement, require additional information.

(I) Application to Manufacture a New Controlled Substance. Any person who proposes to manufacture a controlled substance for which he is not registered with the Bureau of Narcotics and Dangerous Drugs, shall file with the Commissioner a copy of BND Form 130, which shall be treated as confidential by said Commissioner.

(1) He shall file a copy thereof at the time he files such form with the Bureau of Narcotics and Dangerous Drugs or before he begins manufacture, whichever is earlier.

(2) The applicant need not disclose any technical detail of the process which he regards as a trade secret but he must identify each substance used in or resulting from successive stages of manufacture, in order to notify the Commissioner of precursors and byproducts.

(J) Termination of Registration. The registration of any person shall terminate if and when such person dies or ceases legal existence or discontinues business or professional practice in Massachusetts or changes his name or address as shown on the registration, or has his registration revoked by the Commissioner.

(1) In the event of a change in name or address, the person may apply for a new registration in advance of the effective date of such change.

(2) Any registrant who ceases legal existence, or discontinues business or professional practice, or changes his name or address as shown on the Certificate of Registration shall notify the Commissioner at least 30 days before such event and shall surrender his Certificate of Registration by mailing it to the Commissioner on the day of such event.

(3) The executor of the estate of any deceased registrant shall surrender the deceased's Certificate of Registration by mailing it to the Commissioner as soon as feasible.

(K) Transfer of Registration Prohibited. No registration or any authority conferred thereby shall be assigned or otherwise transferred.

(L) Suspension or Revocation of Registration. The Commissioner may suspend or revoke a registration issued by him to manufacture distribute, dispense or possess a controlled substance:

(1) After a hearing pursuant to the provisions of M.G.L. c. 30A upon a finding that the registrant:

(a) Has furnished false or fraudulent material information in any application filed under the provisions of 105 CMR 700.000, or

(b) Has been convicted under any state or federal law of any criminal violation relating to his fitness to be registered under this chapter, or

(c) Has had his federal registration suspended or revoked to manufacture, distribute, dispense, administer or possess controlled substances, or

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(d) Is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense or possess any controlled substance, or

(2) Pursuant to the provisions of M.G.L. c. 94C, § 13 for violation of any provision of M.G.L. c. 94C.

(M) Registration Number. The Massachusetts registration number of any person registered with the Bureau shall be the same as the registration number or one of the registration numbers assigned by said Bureau, as determined by the Commissioner.

(1) The Commissioner shall assign a Massachusetts registration number to any registrant not registered with the Bureau until such person is assigned a number by said Bureau, at which time the number assigned by the Commissioner automatically will become void.

(N) Registrations Effective as of July 1, 1972. Notwithstanding any other provision of these regulations, on and after July 1, 1972 a person shall be deemed to be registered with the Commissioner, until duly registered otherwise by the Commissioner or until the Commissioner informs him that he is not registered, or until August 31, 1972, whichever is earliest, provided that:

(1) If he holds at any time between July 1, 1972 and August 1, 1972 a valid registration issued by the Bureau, he shall be registered for the activities for which he is registered with said Bureau, for the Schedules for which he is registered with said Bureau, and for Massachusetts Schedule VI, or

(2) If he is a physician, dentist, podiatrist or veterinarian who is duly authorized to practice his profession in the Commonwealth and is not registered with the Bureau, he shall be registered to dispense Massachusetts Schedule VI other than for research pursuant to M.G.L. c. 94C, § 8, or

(3) If it is a health facility or part of a health facility which is licensed by the Department of the Department of Mental Health and possesses controlled substances which are safeguarded for or intended to be dispensed to any patient in such facility, in accordance with the regulations of the Department (105 CMR) or the Department of Mental Health (104 CMR), as applicable, it shall be registered to dispense controlled substances in accordance with such regulations.

700.005: Security Requirements

(A) Physical Security Requirements. All applicants and registrants shall provide effective physical security controls against theft and other diversion of controlled substances. All applicants and registrants shall provide physical security controls which meet the conditions of the Director of the Bureau of Narcotics and Dangerous Drugs.

(B) Personnel Security Requirements. All applicants and registrants shall screen before employement new employees who may work in or around areas where controlled substances are handled.

(1) Such screening shall be made solely for the purpose of determining whether the prospective employee is a responsible person. Documentation of such screening shall be made available by applicants and registrants to the Commissioner upon his request.

(2) No registrant shall knowingly employ any agent or employee who has had an application for registration denied for violation of any law or regulation or has had his registration revoked for violation of any law or regulation at any time.

(C) Security of Mail. Every registrant shall ensure that mail which can reasonably be believed to contain controlled substances and which is addressed to any person at the registrant's place of business or professional practice, is safeguarded until delivered directly to the addressee, or immediately returned to the sender.

(D) Report of Theft or Loss. A registrant shall report the theft or loss of any controlled substances to the designated agent of the Commissioner by telephone upon discovery of such theft or loss, and shall submit to said Commissioner a copy of "Report of Theft of Controlled Substances" (BND Form 106), within seven days of such theft or loss.

700.006: Requirements for Records, Inventories, and Reports

(A) Records Required, Generally. Every person registered with the Commissioner shall keep records, maintain inventories, and make reports in conformance with the requirements of the Federal "Comprehensive Drug Prevention and Control Act of 1970" or any amendment thereof and the Federal Food, Drug and Cosmetic Act, and with any additional regulations promulgated by the Commissioner.

(B) Time for Keeping Records. A registrant shall keep for at least two years from the date of preparation, every report, inventory and record he is required to keep by 105 CMR 700.000.

(C) Central Record Keeping. Any registrant may keep central records if he holds a valid permit to keep central records issued by the Bureau of Narcotics and Dangerous Drugs and notifies the Commissioner thereof.

(D) Exemptions from Record Keeping. A registered person who uses any controlled substance in research or teaching at a registered institution which maintains records, is exempt from the requirement to keep his own records, if he has notified the Bureau and the Commissioner of the name, address and registration number of the institution registered by the Bureau, which maintains his records; and a registered chemical analyst employed by a scientific laboratory which maintains records, is exempt from the requirement to keep his own records if he has notified the Commissioner of the name, address and registration number of the scientific laboratory which maintains his records.

(E) Inventory Requirements. Every registrant shall take an initial inventory and biennial inventories thereafter.

(1) Every registrant required to take inventories under Federal Law and Regulations shall follow those requirements, which are deemed to include Schedules I, II, III, IV, and V only.

(2) Every registrant who was not a registrant on August 1, 1972 and is not required to take inventories under Federal Law and Regulations shall take an initial inventory of all his controlled substances in Schedules I, II, and III on the day he first engages in the manufacture, distribution, or dispensing of controlled substances.

(3) Every registrant shall take a new inventory of all stocks of controlled substances in Schedules I, II, and III every two years following the date on which either the Federal or State initial inventory was taken, as applicable:

(a) On the day of the year on which the initial inventory was taken, or

(b) On the registrant's regular physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date and which would otherwise apply, or

(c) Any other fixed date which does not vary by more than six months from the biennial date which would otherwise apply.

(4) A registrant who elects to take his biennial inventory on his regular general physical inventory date or another fixed date, shall notify the Commissioner of this election and of the date on which he will take his biennial inventory.

(5) Whenever the Commissioner by regulation adds to any schedule a controlled substance which was not immediately prior to that date listed in a schedule on which a registrant was required to keep records, a registrant who possesses that substance shall:

(a) Take on the effective date of the regulation an inventory of all stocks of that substance on hand, and;

(b) Thereafter, include such substance in each inventory made by such registrant.

(F) Additional Records and Inventories Required of Practitioners. A registered physician, dentist, podiatrist, veterinarian, certified nurse midwife, nurse practitioner, psychiatric nurse or physician assistant shall maintain records and inventories in accordance with these regulations, with respect to all controlled substances in Schedules I, II, and III which he dispenses or administers in any manner, any exemptions for individual practitioners in Federal law and regulations notwithstanding.

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(1) A registered physician, dentist, podiatrist or veterinarian shall include in his inventories of controlled substances in Schedules I, II, and III the following information:

(a) For each controlled substance in finished form:

1. The name of the substance, and
2. The size of each finished form in metric weight or volume, and
3. The number of units or volume of each finished form.

(b) For each controlled substance not in finished form:

1. The name of the substance, and
2. The total quantity of the substance to the nearest metric unit of weight.

(2) Records maintained by registered physicians, dentists, podiatrists, certified nurse midwife, nurse practitioners, psychiatric nurse and physician assistants shall be closed to the public, and shall not be used in the criminal prosecution of any person in connection with his treatment as a patient by such physician, dentist, podiatrist, certified nurse midwife, and nurse practitioner, psychiatric nurse or physician assistant nor shall they be admissible in evidence against any such patient in connection with such treatment in any criminal, civil, legislative or administrative proceeding.

(3) Practitioner Records for Schedules I, II and III. A registered individual practitioner shall maintain on a current basis, separately for each registration he/she possesses, a complete and accurate record of each substance in Schedules I, II, and III received, distributed, administered, dispensed, and otherwise disposed of as follows:

(a) The name of the substance and the form of the substance, and

(b) The size of each finished form in metric weight or volume, and

(c) The number of units or volume of each finished form received from other persons; the date received; and the name, address, and Bureau registration number of the person from whom the substance was received, and

(d) The name, dosage and strength per dosage unit of each controlled substance administered or dispensed; the name and address of the person for whom the controlled substance was administered or dispensed and whether administered or dispensed by delivery or dispensed by prescription; the date of the administration or dispensing, and the written or typewritten name or initials of the person who administered or dispensed the substance, and

(e) The number of units or volume of such finished forms disposed of in any other way by the registrant, including the date and manner of disposal.

(4) Practitioner Records for Schedules IV and V. A registered individual practitioner shall maintain records, as described in 105 CMR 700.006(F)(3)(a) through (e), of controlled substances listed in Schedules IV and V which are dispensed, other than by prescribing or administering, in the lawful course of professional practice.

(5) Practitioner Records for Schedule VI. A registered individual practitioner, including an optometrist, who dispenses, other than by prescribing and administering, Schedule VI sample medications shall maintain a record, which may be kept in the patient's medical record, of the following information:

(a) the name, dosage and strength of the substance dispensed;

(b) the volume of units dispensed;

(c) the date of the dispensing; and

(d) the name and address of the person to whom the medication was dispensed.

(6) Record Keeping Requirements for Schools Registered for Fluoride Programs. Schools shall keep for a period of two years such records concerning the administration of fluoride tablets and mouthrinse as the Commissioner may require.

(G) Additional Reporting Required by Manufacturers. Each registered manufacturer shall submit to the Commissioner on forms approved or supplied by him, a quarterly report, on or before the 15th day of the month succeeding the period for which such report is submitted, accounting for all stocks of non-narcotic controlled substances appearing in Schedules I, II, and III on hand at the beginning and at the end of the quarter, and for all receipts, dispositions, manufacturing and packaging of such controlled substances. Such reports shall be made in a form as similar as possible to the Federal reporting requirements for narcotic controlled substances appearing in Schedules I, II, and III. Each registered manufacturer shall make available to the Commissioner the required Federal reports for narcotic controlled substances in schedules I, II, and III.

700.006: continued

(H) Distribution upon Discontinuance of Business or Professional Practice. Any registrant who desires to cease legal existence or discontinue business or professional practice or move his principal place of business or professional practice from the Commonwealth shall notify the Commissioner in writing at least 15 days before such event, and shall inform the Commissioner how he proposes to dispose of all the controlled substances in his possession. If the Commissioner does not notify the registrant by the date the registrant has proposed to dispose of such substances that he should postpone or cancel such disposal he may proceed as he proposed to the Commissioner. Any such registrant, any registrant whose registration has expired, the executor of the estate of any deceased person in possession of controlled substances, any registrant in possession of controlled substances which are safeguarded for or intended to be dispensed to any patient who has died, or been transferred from the jurisdiction of the registrant without such controlled substances being transferred, and any other person in possession of controlled substances for which he is not registered:

(1) Shall dispose of all controlled substances in his possession:

(a) Under the authorization and instructions of the Regional Director of the Bureau by transfer to a person registered to possess the controlled substances, or

(b) By delivery to an agent of the Bureau, or

(c) By delivery to an expressly authorized agent of the Commissioner, or

(d) By destruction of the substances in the presence of an agent of the Bureau, or

(e) By destruction of the substances in the presence of an expressly authorized agent of the Commissioner, or

(f) By such other means as said Regional Director may determine, and

(2) May transfer such controlled substances in accordance with 105 CMR 700.006(H)(1) without being registered to do so, and

(3) Upon the completion of such disposition, shall file with the Commissioner on a form approved or provided by him a final report of such disposition.

(I) Filing of Prescriptions by Pharmacies in Registered Health Facilities. Every pharmacy located in a health facility registered with the Commissioner shall file prescriptions for controlled substances as follows:

(1) Prescriptions for controlled substances listed in Schedules I and II shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedules I and II only;

(2) Prescriptions for controlled substances listed in Schedules III, IV, and V shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule III, IV and V only; and

(3) Prescriptions for controlled substances listed in Schedule VI and prescriptions for non-controlled substances shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule VI and non-controlled substances.

(J) Prescription Monitoring Program.

(1) Pharmacy Reporting Requirements.

(a) Every pharmacy located in a health facility registered with the Commissioner that dispenses controlled substances in Schedule II pursuant to a prescription, shall transmit to the Department or its agent the following information for each such prescription:

1. pharmacy prescription number;
2. pharmacy number (NABP);
3. patient identifier, where feasible;
4. date the controlled substance is dispensed;
5. metric quantity of controlled substance dispensed;
6. national drug code (NDC) of controlled substance dispensed;
7. estimated days supply of controlled substance dispensed; and
8. prescriber's U.S. Drug Enforcement Administration (DEA) registration number.

105 CMR 700.006(J) shall not apply to medication orders in hospitals.

700.006: continued

(b) The pharmacist shall make a good faith effort to verify the patient identifier of the person to whom the prescription for a controlled substance in Schedule II is delivered, in accordance with professional standards and personal judgment.

(c) The information required by 105 CMR 700.006(J) shall be transmitted to the Department or its agent no later than 15 days following the last day of the month in which the prescription was dispensed by use of:

1. electronic device, computer diskette, or magnetic tape, each in a format approved by the Department, or other acceptable electronic method approved by the Department; or,
2. Universal Claim Form.

(d) Pharmacies reporting data from 25 or more prescriptions in any given month must provide the required information in accordance with 105 CMR 700.006(J)(1)(c)1.

(e) The Department may grant a waiver to a pharmacy which is unable to transmit the required data in accordance with 105 CMR 700.006(J)(1)(c)1. for a period of 180 days, which 180 day period may be extended by the Department at its discretion. During the effective period of the waiver and any extension granted by the Department, the pharmacy must submit the required data in a format acceptable to the Department.

(2) Prescription Monitoring Program Advisory Board.

(a) The Commissioner of the Department of Public Health shall establish a Prescription Monitoring Program Advisory Board to assist in the implementation of 105 CMR 700.006(J) and any other related regulations. The membership of this Advisory Board shall include representatives of the Department of Public Health; Executive Office of Public Safety; disciplinary authorities, including the Boards of Medicine, Pharmacy, Dentistry, Podiatry, and Veterinary Medicine; representatives of associations or societies representing professions authorized to issue or dispense prescriptions, patient interests, and privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(b) The Prescription Monitoring Program Advisory Board shall assist the Department in designing education programs for the proper use of Schedule II drugs.

(3) Prescription Monitoring Program Medical Review Group.

(a) The Commissioner shall establish Prescription Monitoring Program Medical Review Groups, to provide accepted medical practice standards for the implementation of 105 CMR 700.006(J) and related regulations. The membership of each Medical Review Group shall consist of two or more registered practitioners, one of whom shall be affiliated with a health care facility, and at least one registered pharmacist. In all cases, members of the Medical Review Groups shall be registered health care practitioners and a majority shall be registered in the same discipline as the practitioner whose records are under review. Registered practitioners shall be designated by the Commissioner from lists approved by the appropriate Boards of Registration in the discipline under which records will be reviewed. Such lists shall be provided by the respective statewide professional societies, whose membership shall fully represent the complete geographic and practice differences represented in the state as a whole.

1. In the event that insufficient listings are available to comprise the appropriate membership of any particular Medical Review Group, the Commissioner may appoint additional members.
2. Whenever possible, the practitioners on a particular Medical Review Group shall be specialists, as designated by a national accrediting board acceptable to the Commissioner, in the same field as the practitioner whose records are being reviewed.
3. In all cases, practitioners serving on the Medical Review Group must have a valid Controlled Substance Registration for prescribing Schedule II drugs, pursuant to M.G.L. c. 94C, § 18.

(b) The Medical Review Group shall assist the Department in the evaluation of prescription information.

700.006: continued

(4) Privacy and Confidentiality.

(a) Except where otherwise provided by law or judicial order, the information collected pursuant to 105 CMR 700.000 shall not be disseminated to anyone other than:

1. a duly authorized representative of the board or agency responsible for registration, regulation or discipline of practitioners authorized to prescribe or dispense schedule II controlled substances acting in accordance with their official duties;

2. a law enforcement agency when acting in accordance with its official duties in conducting a bona fide criminal investigation or prosecution of criminal violations. Requests for inspection of these records shall first be directed to the Office of the Attorney General of Massachusetts, or to the Massachusetts State Police Diversion Investigation Unit, or the United States Drug Enforcement Administration, for notification and approval prior to action by the Department;

3. an individual who is the data subject that has access to this data pursuant to a statute or regulation of the Commonwealth.

(b) All requests for information collected pursuant to 105 CMR 700.006(4)(a)2. must be in writing. All such information generated shall be reviewed and approved by the Commissioner and the Medical Review Group prior to release by the Department.

In the event that the Department, through computer analysis and review of the records generated by the prescription monitoring program, finds patterns of prescribing which raise questions regarding the behavior of patients, pharmacists or practitioners, the Department shall provide such information to the appropriate Medical Review Group for further review or referral, as provided for in 105 CMR 700.006(J)(4)(a)1. and 2.

700.007: Inspection of Premises

(A) Notice of Inspection Required. The Commissioner or any expressly authorized agent of his may carry out an inspection relating to any provision of the chapter of a registrant or applicant for registration, upon stating his purpose, presenting his appropriate credentials, and presenting a Notice of Inspection to the owner, operator or agent in charge of the premises to be inspected, if he is given in writing the informed consent of such owner, operator or agent in charge.

(B) Notice of Inspection Form. The Notice of Inspection Form shall be supplied by the Commissioner and shall contain:

(1) The name and title of the registrant.

(2) The name and title of the owner, operator or agent in charge if different from the registrant.

(3) The name, if any, and address of the controlled premises.

(4) The date and time of the inspection.

(5) A statement that the Notice of Inspection is given pursuant to M.G.L. c. 94C.

(6) A reproduction of the pertinent parts of M.G.L. c. 94C.

(7) The signature of the inspector.

(8) Provision for acknowledgement in writing by the owner, operator or agent in charge of the controlled premises that he has given his informed consent. Such acknowledgement shall contain a statement for the owner, operator or agent in charge that he has been informed:

(a) Of his constitutional right not to have an administrative inspection of the premises without an administrative inspection warrant;

(b) Of his right to refuse such an inspection;

(c) Of the possibility that anything of an incriminating nature which may be found may be used against him;

(d) That he has been presented with a Notice of Inspection in accordance with 105 CMR 700.000,

(e) That the consent given by him is voluntary and without threats of any kind; and

(f) That he may withdraw his consent at any time during the course of inspection.

700.007: continued

(C) Notice of Inspection Distribution. The Notice of Inspection and acknowledgement of informed consent shall be made in duplicate and one copy shall be retained by the Commissioner and the duplicate shall be given to the person inspected.

(D) Confidentiality of Trade Information. Unless the owner, operator, or agent in charge of a controlled premises so consents in writing, no inspection authorized by 105 CMR 700.000 shall extend to:

(1) Financial data, or
(2) Sales data, other than shipping data, or
(3) Pricing data, or
(4) Technical details of production processes other than as specified in 105 CMR 700.004(I): *Application to Manufacture a New Controlled Substance.*

700.008: Requirements Regarding Hypodermic Instruments

(A) License "to sell". No person except a registered physician, dentist, nurse, veterinarian, embalmer, pharmacist, wholesale druggist, or a registered podiatrist certified by the Board of Registration in Podiatry to be competent to use hypodermic needles, shall sell, offer for sale, deliver or have in possession with intent to sell hypodermic syringes, hypodermic needles or any instrument adapted for the administration of controlled substances by injection, unless licensed to do so by the Department.

(1) A license "to sell" shall be:
  (a) Valid for one year, and
  (b) Required at only one location for a company or corporation.
(2) The fee for a license "to sell" shall be $10.00.

(B) License "to purchase". No person except a registered physician, dentist, veterinarian, pharmacist, wholesale druggist, manufacturing pharmacist, pharmaceutical manufacturer, embalmer, or a manufacturer of or dealer in surgical supplies, official of any government agency requiring the use of such instrument by reason of his official duties, a nurse upon the written order of a physician or dentist, or a manufacturer of or dealer in embalming supplies, or a podiatrist certified by the Board of Registration in Podiatry to be competent to use hypodermic needles, a registered chemical analyst, an employee of a hospital or scientific institution upon the written order of its superintendent or an officer in immediate charge of a licensed person, a researcher registered pursuant to M.G.L. c. 94C, § 7, or a person who has received a written prescription to purchase a hypodermic instrument, shall obtain, receive, or puchase a hypodermic syringe, hypodermic needle or any instrument adapted for the administration of controlled substances by injection, unless licensed so to do by the Department or by a local board of health.

(1) A license "to purchase" issued by the Department shall be:
  (a) Valid for one year
  (b) Valid throughout the Commonwealth
(2) The fee for a license "to purchase" issued by the Department shall be $5.00.

(C) Application for License. A person who wishes to obtain a license to sell hypodermic instruments or a person who wishes to obtain a license issued by the Department to purchase hypodermic instruments, shall apply to the Department in an application form supplied or approved by the Commissioner.

(1) The application form shall indicate:
  (a) Whether the license is to sell, to purchase, or both, and
  (b) The 1. name, 2. address, 3. business or profession of the applicant, 4. purpose for which the applicant wishes the license, and 5. applicant's Bureau registration number, if any.

700.008: continued

(D) Extension of Licenses. Notwithstanding any other provisions of these regulations a license to sell, offer for sale, deliver, or be in possession with intent to sell hypodermic syringes, hypodermic needles, or any instrument adapted for the administration of controlled substances by injection, and any license to obtain, receive, or purchase a hypodermic syringe, hypodermic needle or any instrument adapted for the administration of a controlled substance, issued by the Department or by a local board of health on or before June 30, 1972, shall be deemed to be valid until the time it would have otherwise expired.

700.009: Research Involving Controlled Substances

Research projects and studies covered by M.G.L. c. 94C, § 8 shall be carried out in accordance with the regulations of the Commissioner.

(A) Persons Covered. No person, unless he supplies the Commissioner and the Commissioner of Mental Health (a) with satisfactory evidence of compliance with any applicable Federal law, and (b) with a protocol describing the research project or study to be undertaken if the Commissioner so requires shall carry out any research project, or study involving:

(1) Any narcotic drug in Schedule II or

(2) The investigational use on human beings of any new drug as defined in § 201(p) of the Federal Food, Drug and Cosmetics Act, as amended.

(B) Information to Be Submitted. The person immediately responsible for a research project or study covered by M.G.L. c. 94C, § 8, before commencing any such research project or study shall submit to the Commissioner and to the Commissioner of Mental Health:

(1) Satisfactory evidence of compliance with any applicable Federal law, as described in 105 CMR 700.009(C), and

(2) A proposed written "Statement of Informed Consent", and

(3) A statement of "Assurance of Compliance" with the requirements for the protection of human research subjects by an Institutional Review Committee, pursuant to 105 CMR 700.009(F) and 700.009(G), and

(4) A protocol describing the research project or study to be undertaken if the Commissioner so requires, and

(5) Such further information as the Commissioner, in his discretion may require.

(C) Evidence of Compliance with Applicable Federal Law. Satisfactory evidence or compliance with applicable Federal Law shall consist of:

(1) Any of the following which are required by the Federal Food and Drug Administration:

(a) Notice of Claimed Investigational Exemption for a New Drug (Form FD 1571); and

(b) Statement of Investigator (Clinical Pharmacology) (Form FD 1572); and

(c) Statement of Investigator (Form FD 1573); and

(2) A copy of the Bureau Registration of each person required to be registered by the Bureau.

(D) Protection of Human Subjects. No person shall undertake any research project or study covered by M.G.L. c. 94C, § 8 unless:

(1) The rights and welfare of all human subjects are adequately protected, and

(2) The risks to any human subject are outweighed by the potential benefits to him or by the potential benefits to mankind, and

(3) Every human subject has given his written "Statement of Informed Consent", by signing a written statement describing:

(a) The nature, duration and purpose of the investigation, and

(b) The method and means by which the investigation is to be conducted, and

(c) All inconveniences, hazards, discomforts, and risks reasonably to be expected, and

(d) The effects upon the subject's health or person which may reasonably be expected to come from his participation, and

700.009: continued

(e) A description of the controlled substances and other substances to be used, and their anticipated effects, side effects and interactions, and

(f) An identification of those procedures which are experimental, and

(g) A description of the benefits to be expected, and

(h) A disclosure of appropriate alternative procedures which would be advantageous to the subject, and

(i) An offer to answer any inquiries concerning the procedures, and

(j) An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

(E) Statement of Informed Consent. Every written "Statement of Informed Consent" shall:

(1) Contain no exculpatory language, through which the subject is made to waive or appear to waive any of his legal rights or to release an institution or its agents from liability or negligence,

(2) Contain a statement for the subject to sign, that:

(a) He has read the "Statement of Informed Consent", and

(b) He understands the "Statement of Informed Consent" and the attendant risks described, and

(c) He understands he may terminate his consent at any time, and

(d) He voluntarily consents to be a research subject in the described project.

(3) Be obtained from the subject himself unless he is legally incompetant, in which case it may be obtained in writing from his legal representative, and

(4) Not be obtained in any event from a minor who refuses his consent.

(F) Assurance by Institutional Review Committee. No person shall undertake any research project unless an Institutional Review Committee:

(1) By majority vote with the record of the number in favor and the number opposed recorded, and by the signature of an authorized representative signifies its approval of:

(a) The protocol; and

(b) The "Statement of Informed Consent"; and

(2) Describes how it will monitor the person immediately responsible for the research project, including how and when such person will be required to:

(a) Submit written reports or

(b) Appear for interviews or

(c) Be visited by the Institutional Review Committee or its representatives, and

(3) Describes how it will notify the Commissioner regarding any:

(a) Proposed changes or

(b) Emergent problems, including significant hazards, contraindications and side effects.

(G) Institutional Review Committee.

(1) The Institutional Review Committee:

(a) May be an existing body, or

(b) May be specially constituted to review a research project.

(2) The Institutional Review Committee:

(a) Must exist in affiliation with the Department or the Department of Mental Health, or with a hospital licensed or maintained by the Department or the Department of Mental Health or the Commonwealth; and,

(b) Must be composed of at least five members with sufficiently varying backgrounds to assure complete and adequate review of any research project; and,

(c) Must include persons other than health professionals who have no business nor professional connection with such agency or hospital as not less than ⅛ of its members; and,

(d) Must include documentation to identify the committee members by name, occupation or position, and by indications of experience and competence in areas pertinent to the areas of review.

(3) No member of such committee shall be involved in either the initial or continuing review of an activity in which he has a professional responsibility, except to provide information requested by the committee.

700.009: continued

(H) Protocol.

(1) The protocol shall describe:

(a) The identification and qualifications of the person in charge of the research project, and

(b) The objectives of the research project or study, and

(c) The procedures to be used, including:

1. The pertinent diagnostic classification or a description of the symptom or syndrome characteristics, of the human research subjects under investigation with a statement as to their general health status; and

2. The age range of the research subjects and whether one sex or both sexes will be used; and

3. Each specific controlled and any other substance which has not been approved by the Federal Food and Drug Administration for safety and effectiveness for use on humans to be used in the study; the forms in which the substances are supplied; and the methods by which the substances are to be administered or dispensed; and

4. The dosage range of each substance to be dispensed or administered, by either describing the specific dosage units, or the rate of administration, or the daily dosage regimens and the maximum period for which it will be dispensed or administered; and

5. The overall research design model to be employed; and

(d) The institutions or places where the project will be conducted or from which the substances will be dispensed or administered, and

(e) The projected period of time to complete the study, and

(f) The procedures to be used to ensure the security of the controlled substances; and

(g) Any other pertinent data or clarification which the Commissioner in his judgement may require or request.

(I) Requirement of Confidentiality. Records maintained by researchers, including every "Statement of Informed Consent", shall be closed to the public, and shall not be used in the criminal prosecution of any research subject in connection with his participation as a research subject, nor shall they be admissible in evidence against any such research subject in connection with such participation in any criminal, civil, legislative or administrative proceeding.

(J) Request to Inspect Protocol. If a request is made to inspect and/or release one of the protocols on file with the Department, the Department shall promptly notify the researcher and the pharmaceutical company(nies) sponsoring the clinical trial of the request, by telephone and followed up by written notification by certified mail. Such notification shall not include the identity of the person requesting inspection unless otherwise required by law, but may in the discretion of the Department include any known connection of the requesting party to organizations or entities with a competing commercial interest. In the case of a general request for inspection involving more than a specified researcher, protocol, drug or pharmaceutical company, and association representing pharmaceutical manufacturers and/or researchers may be notified in lieu of individual researchers and pharmaceutical manufacturers. Notification shall be at least eight calendar days prior to inspection.

700.010: Dispensing and Labelling of Sample Medications by Practitioners

(A) A registered individual practitioner may in the course of professional practice dispense to an ultimate user the following:

(1) A Schedule VI sample medication in a single dose or in such quantity as is in the opinion of the practitioner appropriate for the treatment of the patient but not exceeding a 30 day supply per dispensing; provided, however that this quantity may be increased to a 90 day supply if dispensed as part of an indigent patient drug program and deemed appropriate in the professional judgement of the practitioner;

(2) A Schedule II-V sample medication in a single dose or in such quantity as in the opinion of the practitioner is essential for the immediate treatment of the patient.

700.010: continued

(B) All sample medications dispensed by a registered individual practitioner shall be properly labeled.

(1) Whenever a sample medication is dispensed by a practitioner, a label shall be affixed to the outside of the package, and shall include the following information:

(a) practitioner's name and address;

(b) date of dispensing; and

(c) name of the patient, unless a veterinary product.

(2) In addition, the following information must be included on the label unless already provided for on the manufacturer's packaging of the sample medication:

(a) name, dosage form and strength of the sample medication;

(b) clear, simple and brief directions for use and any necessary cautionary statements; and

(c) date on which the medication will expire.

(3) Information provided to the patient under 105 CMR 700.010(B)(2) shall be, in the professional judgement of the practitioner, presented in a manner which can be easily understood by the patient. A combination of written information, labeling and counseling may be used to meet this requirement, based upon the individual needs of each patient.

(4) If multiple packages of the same sample medication are dispensed at the same time to the same patient, the samples may be placed in a larger container to which the label containing applicable information required by 105 CMR 700.010 has been affixed.

700.011: Issuance of Prescriptions or Medication Orders for Implantable Infusion Pumps Containing Schedule II or Schedule III Controlled Substance

A prescription or medication order for an implantable infusion pump containing a Schedule II or Schedule III controlled substance may be filled for a maximum of a 90 day supply.

700.020: Severability

The provisions of 105 CMR 700.000 are severable, and if any provision shall be in violation of any Federal rule or regulation or any Federal or Massachusetts law, such provision shall be null and void and such violation shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 700.000: M.G.L. c. 94C, § 2.

105 CMR 701.000: REGULATIONS ADOPTED JOINTLY BY THE DEPARTMENT OF PUBLIC HEALTH AND THE BOARD OF REGISTRATION IN PHARMACY FOR THE IMPLEMENTATION OF M.G.L. c. 94C

Section

701.001: Excluded Non-Narcotic Substances
701.002: Excepted Compounds
701.003: Emergency Situations in Which Controlled Substances in Schedule II May Be Dispensed upon Oral Prescription

701.001: Exluded Non-Narcotic Substances

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act be lawfully sold over the counter without a prescription, are excluded from all schedules.

Table 1.

Amodrine	Tablet: Phenobarbital, 8mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G.D. Searle & Co.
Bronkaid	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Drew Pharmacal Co., Inc.
Bronkolixir	Elixir (5cc); Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl guaiacolate, 50 mg.; theophylline, 15 mg.; chlorpheniramine maleate, 1 mg.	Breon Laboratories, Inc.
Bronkotabs	Tablet: Phenobarbital, 8 mg., ephedrine sulfate, 24 mg.; glyceryl gualacolate, 100 mg.; theophyline, 100 mg.; thenyldiamine, 10 mg.	Do.
Primatene	Tablet: Phenobarbital, ⅛ gr.; ephedrine ⅜ gr.	Whitehall Laboratories
Tedral	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories
Tedral Anti-H	Tablet: Phenobarbital, 8 mg. chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.

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Tedral ½ strength	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg.; ephedrine hydrochloride, 12 mg.	Do.
Tedral Pediatric Suspension	Suspension (5cc); Phenobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength	Suppository: Phenobarbital, 16 mg.; theophylline 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tederal suppositories regular strength	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Verequad	Tablet: Phenobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacoate, 100 mg.	Knoll Pharmaceutical Co.
Verequad	Suspension (5cc): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 50 mg.	Do.

701.002: Excepted Compounds

(A) The following drugs in dosage unit form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant, or hallucinogenic effect, and which are restricted by law to dispensing on prescription, are excepted from all schedules except Schedule VI.

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A.	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Alased	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried 7½ gr.: magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Alcitex	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 3⅛gr., magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories, Inc.
Alhydrox	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply
Alkasans	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P.J. Noyes Co.
Alsical	Powder (60 gr.): Phenobarbital, ⅛ gr.; belladonna extract, ⅛ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hydroxide gel, dried, 10 gr.	Dorsey Laboratories
Alubelap	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 300 mg.; belladonna extract, 4 mg.	Haack Laboratories, Inc.
Aludrox SA Suspension	Suspension (5 cc): Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories
Aludrox SA Tablets	Tablet: Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories
Alu-Mag	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ⅛ gr.	Norsal Laboratories, Inc.
Alumazen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg., aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate and kaolin with phenobarbital and atropine sulfate	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, collodidal, 2 gr.; atropine sulfate, 1/300 gr.	Buffalo Pharmaceutica Supply Corp.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Aminodrox with Phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm.; aluminum hydroxide gel, dried, 0.12 gm.	The S.E. Massengill Co.
Aminodrox-Forte with Phenobarbital	Tablet: Phenobarbital, 15 mg. aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	Do.
Aminophylline and Amytal	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly Co.
Aminophylline with pentobarbital	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G.D. Searle & Co.
Aminophylline and phenobarbital Do.	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg. Tablet: Phenobarbital, ⅛ gr.; aminophylline, 100 mg.	The Zemmer Co. The Blue Line Chemical Co.
Aminophylline with phenobarbital Do. Do.	Tablet: Phenobarbital, 16 mg.; aminophylline 100 mg. Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg. Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	H.E. Dubin Laboratories, Inc. G.D. Searle & Co. Do.
Aminophylline with phenobarbital	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	Do.
Amobarbital and PETN	Capsule: Amobarbital, 50 mg.; pentoerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with Butabarbital Sodium (AMPYROX)	Tablet: Butabarbital sodium, 15 mg.; scopolamine methyinitrate, 2 mg.	Paul B. Elder Co., Inc.
Ampyrox with Butabarbital Sodium, Elixir	Elixir (5cc); Butabarbital sodium, 10 mg.; scopolamine methyinitrate, 1 mg.	Do.
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr. hyoscine hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmacal, Inc.
Amsodyne	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ⅛ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder., Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Antacia No. 3 with Phenobarbital and Atropine	Tablet: Phenobarbital, 1/6 gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 5 gr., magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic	Tablet: (purple): Phenobarbital, 16.2 mg.; nyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyoscine hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-Enzyme	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0619 mg.; homatropine methylbromide, 0.2885 mg.; hyoscine hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Do.
Antrocol	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-Plus, Children	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 1⅞ gr.	The Wm. A Webster Co.
Aqualin-Plus No. 1	Suppository: Pentobarbital sodium, ¾ gr., theophylline, 3¼ gr.	Do.
Aqualin-Plus No. 2	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-Plus No. 2A	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 7½ gr.	Do.
Asmabar	Tablet: Butabarbital, 20 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Asmacol	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanoiamine hydrochloride, 25 mg.; chlopheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Asperease Modified with Phenobarbital	Tablet: Phenobarbital, 0.008 0.008 gm.; acetylsalicyclic acid, 0.5 gm.	P.J. Noyes Co.
Atropal	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; magnesium trisiicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Mallinckrodt Chemcial Works
Atrosilital	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm., saccharin sodium, 0.12 mg.	The Zemmer Co.
Banthine with Phenobarbital	Tablet, Phenobarbital, 15 mg.; methantheline bromide, 50 mg.	G.D. Searle & Co.
Barbatro No. 1	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S.E. Massengill Co.
Barbatro No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscine hydrobromide, 0.007 mg., homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna Elixir	Elixir (5cc); Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1288 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Mallinckrodt Chemical Works
Barbidonna Tablets	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1288 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Do.
Barboma Elixir	Elixir (100 cc); Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma Tablets	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, ¼ gr.	Do.
Bardase	Tablet or elixir (4 cc): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyosine hydrobromide, 0.007 mg., atropine, 0.020 mg., Taka-Diastase, 162.0 mg.	Parke, Davis & Co.

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Trade name or other designation	Composition	Manufacturer or supplier
Bar-Don Elixir	Elixir (30 cc); Phenobarbital, 100 mg., hyoscyamine hydrobromide, 0.60 mg., hyoscine hydrobromide, 0.042 mg., atropine sulfate, 0.12 mg.	Warren-Teed Pharamaceuticals Inc.
Bar-Don Tablets	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscine hydrobromide, 0.007 mg., atropine sulfate, 0.020 mg.	Do.
Belap No. 0	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Haack Laboratories, Inc.
Belap No. 1	Tablet: Phenobarbital, 15 mg., belladonna extract, 8 mg.	Do.
Belap Ty-Med	Tablet: Amobarbital, 50 mg.; homatropine metylbromide, 7.5 mg.	Do.
Belladenal Do.	Tablet: Phenobarbital, 50 mg.; bellafoline, 0.25 mg. Elixir (15cc); Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Sandoz Pharmaceuticals Do.
Bellatol Elixir	Elixir (5cc); Butabarbital sodium, 20 mg., tincture belladonna 0.83 cc.	The Zemmer Co.
Bellergal Do.	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg., levorotatory alkaloids of belladonna, 0.1 mg. Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Sandoz Pharmaceuticals Do.
Beplete with Belladonna Elixir	Elixir (4 cc); Phenobarbital, 15 mg.; vitamin B_1, 1.5 mg.; vitamin B_3, 1 mg.; vitamin B_6, 0.33 mg.; vitamin B_{12}, 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories
Bexadonna	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscine hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals

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Trade name or other designation	Composition	Manufacturer or supplier
Bilamide	Tablet: Phenobarbital, 1/8 gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr., homatropine methylbromide, 1/4 gr.	Norgine Laboratories, Inc.
Binitrin	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.0 mg.	The Vale Chemical Co., Inc.
Bioxatphen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital	Capsule: Phenobarbital, 1/4 gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, 1/8 gr.	The Bernard Co.
Buffadyne A-S	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with Barbiturates	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopolamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B.F. Ascher & Co., Inc.
Burrizem	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.

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Trade name or other designation	Composition	Manufacturer or supplier
Butabarbital and hyoscyamine sulfate Do.	Tablet or elixir (5 cc); Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg. Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	McNeil Laboratories, Inc. Do.
Butibel	Tablet or elixir (5 cc): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.); hyoscine hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.	McNeil Laboratories, Inc.
Butibel R-A	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-Gel Suspension	Suspension (15 cc): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg.; (total alkaloids 0.187 mg.); activated attapulgite, 1.5 mg.; pectin, 75 mg.	Do.
Butibel-Gel Tablets	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 500 mg.; pectin, 45 mg.	Do.
Butibel-Zyme	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic emzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butigetic	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.

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Trade name or other designation	Composition	Manufacturer or supplier
Calergot P-R Do.	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg. Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Sandoz Pharmaceuticals Do.
Cal-Ma-Phen	Tablet: Phenobarbital, ⅛ gr.; calcium-carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply Co.
Cantil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with Phenobarbital and Atropine	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P.J. Noyes Co.
Cardalin-Phen	Tablet: Phenobarbital, gr.; aminophylline, 5 gr.; aluminum hydroxide gel dried, 2½ gr.; benzocaine, ½ gr.	Mallinckrodt Chemical Works
Cardilate-P	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarace	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racephedrine, 20 mg.	Warner-Chilcott Laboratories
Co-Elorine 25	Capsule: Amobarbital, 8 mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, Special	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg.; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Covadil	Tablet: Butabarbital sodium, 20 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Dainite	Tablet: Pentobarbital sodium, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Mallinckrodt Chemical Works
Dainite-KI	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Night	Tablet: Phenobarbital, ⅜ gr.; pentobarbital sodium, ½ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Daricon PB	Tablet: Phenobarbital, 15 mg.; oxyphencyclimine hydrochloride, 5 mg.	Pfizer Laboratories
Diatraegus	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin 1/250 gr.; sodium nitrate, 1 gr.; tincture crataegus, 2 minims.	Buffington's Inc.
Dia-Tropine	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, 1/300 gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with Phenobarbital	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do.	Capsule: Phenobarbital, ½ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories
Donabarb	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ⅛ gr.	Paul B. Elder Co., Inc.
Donaphen, New Special Donaphen	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krone Co.

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Trade name or other designation	Composition	Manufacturer or supplier
Donna-Sed Elixir	Elixir (5 cc): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hysocine hydrobromide, 0.0065 mg.	North American Pharmascal, Inc.
Donnasep	Tablet: Phenobarbital, 8.1 mg.; phenasopyridine hydrochloride, 50.0 mg.; methenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyoscine hydrobromide, 0.0033 mg.	A.H. Robbins Co., Inc.
Donphen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 6 mg.	Lemmon Pharmascal Co.
Dormitol-HM	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, ½ gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with Phenobarbital	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.
Elmaloin with Phenobarbital	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, ⅛ gr.	The Vale Chemical Co., Inc.
Ephedrine sulfate and phenobarbital	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with Phenobarbital	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ⅛ gr.	P.J. Noyes Co.
Ercafital	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 50 mg.	The Blue Line Chemical Co.
Ethrava-trate	Tablet: Mephobarbital, 10 mg.; pentaerythrityl tetranitrate, 20 mg.; ethaverine hydrochloride, 30 mg.	North American Pharmascal, Inc.
Eu-Phed-Amin	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceuticals Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Eu-Phed-Ital	Tablet: Phenobarbital sodium, 30 mg.; ephedrin sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Do.
Fensobel	Tablet: Phenobarbital, 8.1 mg.; belladonna extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 203.5; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin & Pharmaceutical Corp.
Franol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories
Homachol	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg.; ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homopent	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg.; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
H-P-A (Modified)	Tablet: Phenobarbital, ¼ gr.; aspirin, 5 gr.; extract hyoscyamus, ⅛ gr.	Paine Drug Co.
Hybephen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	The S.E. Massengill Co.
Hybephen Elixir	Elixir (5 cc): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	Do.
Hydrochol Plus	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.8 mg.; ox bile desiccated, 50 mg.	Paul B. Elders Co., Inc.
Hytrons Antispasmodic Elixir	Elixir (5 cc): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore

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Trade name or other designation	Composition	Manufacturer or supplier
Hytrona Antispasmodic Tablets	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Ilocalm	Tablet: Mephobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; d-calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with Phenobarbital	Tablet: Phenobarbital, 15 mg.; isosorbide dinitrate, 10 mg.	Ives Laboratories Inc.
Isufranol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories
Isufranol, Mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.
Isuprel Compound Elixir	Elixir (15 cc): Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 45 mg.; potassium iodide, 150 mg.	Do.
Kaphebel	Tablet: Phenobarbital, ⅛ gr.; belladonna root, ¼ gr.; kaolin colloidal, 7½ gr.	Paul B. Elder Co., Inc.
Kanumodic	Tablet: Pentobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulase, 9 mg.; pancrestin, 500 mg.; glutamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories
Kavatrate	Tablet: Phenobarbital sodium, ¼ gr.; veratrum veride, ¼ gr.; mistletoe, ½ gr.; hawthorn tincture, 30 minims; sodium nitrate, 1 gr.	Key Pharmacal Co.
Kie with Phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide, 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Kiophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 150 mg.; potassium iodide, 125 mg.	G.D. Searle & Co.

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Trade name or other designation	Composition	Manufacturer or supplier
Luftodil Suspension	Suspension (5 cc): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl gualacolate, 100 mg.	Mallinckrodt Chemical Works
Luftodil Tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl gualacolate, 200 mg.	Do.
Lufyllin-Ep	Tablet: Phenobarbital, 16 mg.; lufyllin (dyphylline), 100 mg.; ephedrine hydrochloride; 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malglyn Compound	Tablet or suspension (5 cc): Phenobarbital 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Manniphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Manniphen with Rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital	Tablet: Phenobarbital, ¼ gr. mannitol hexanitrate, ½ gr.	P.J. Noyes Co.
Do.	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	The Blue Line Chemical Co.
Maxitol	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.
Meprane Phenobarbital	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick
Meeopin-PB	Tablet or elixir (5 cc): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Metamine with Butabarbital	Tablet: Butabarbital, 16.2 mg.; troinitrate phosphate, 2 mg.	Pfizer Laboratories
Do	Tablet: Butabarbital, 48.6 mg.; troinitrate phosphate, 10 mg.	Do.
Mexal	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.;	The S.E. Massengill Co.
Milpram-200	Tablet: Meprobamate 200 mg.; Conjugated Estrogens - equine 0.4 mg.	Wallace Pharmaceuticals
Milpram-400	Tablet: Meprobamate 400 mg.; Conjugated Estrogens - equine 0.4 mg.	Do.
Milpath-200	Tablet: Meprobamate 200 mg. Tridihexethyl Chloride, 25 mg.	Do.
Milpath-400	Tablet: Meprobamate 400 mg. Tridihexethyl Chloride, 25 mg.	Do.
Miltrate-10	Tablet: Meprobamate 200 mg. Pentaerythritol tetranitrate, 10 mg.	Do.
Miltrate-20	Tablet: Meprobamate 200 mg. Pentaerythritol tetranitrate, 20 mg.	Do.
Monomeb	Tablet: Mephobarbital, 32 mg.; penthlenate bromide, 5 mg.	Winthrop Laboratories
Mudrane	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloride, 16 mg.	Wm. P. Poythress & Co., Inc.
Mudrane GG Elixir	Elixir (5 cc): Phenobarbital, 5.4 mg.; theophylline, 20 mg.; ophedrine hydrochloride, 4 mg.; glyceryl gualacolate, 26 mg.	Do.
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.
Natrona Compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrate, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.

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Trade name or other designation	Composition	Manufacturer or supplier
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg.; homatropine methylbromide, 1.2 mg.	Pitman-Moore
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate, 0.5 gm.	The S.E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacal Co.
Nopheen Tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P.J. Noyes Co.
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg.; calcium lactate, 162 mg.	Lemmon Pharmacal Co.
Oxsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrochloic acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan monooleate, 160 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal Elixir	Elixir (5 cc.); Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, Half Strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric Piptal Antipyretic	Solution (0.6 cc.); Phenobarbital, 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.
Pediatric Piptal with Phenobarbital	Solution (0.5 cc.) ; Phenobarbital, 3 mg.; pipenzolate bromide, 2 mg.	Do.
Pencetylon	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co.,Inc.

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Trade name or other designation	Composition	Manufacturer or supplier
Pentaerythrityl tetranitrate with phenobarbital	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P.J. Noyes Co.
Do.	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentratrol with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmscal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbusem	Tablet: Butabarbital Sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner Chilcott
Do.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with Phenobarbital 8A	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallylbarbituric acid, 16 mg; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophyline, 100 mg.	Buffington's, Inc.
Phenaphen Plus	Tablet: Phenobarbital, 16.2 mg.; phenacetin, 194 mg.; aspirin, 162 mg.; hyoecyamine sulfate, 0.031.; pheniramine maleate, 12.5 mg.; phenylephrine hydrochloride, 10 mg.	A.H. Robbins Co.
Phenobarbital and atropine	Tablet: Phenobarbital, ¼ gr.; strophine sulfate 1/200 gr.	The Blue Line Chemical Co.
Do.	do.	Meyers and Co.
Do.	do.	Paine Drug Co.
Do.	Tablet: Phenobarbital ¼ gr.; atropine sulfate 1/200 gr.	The Vale Chemical Co., Inc.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital with atropine sulfate	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No.2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	Do.
Phenobarbital and atropine sulfate	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Buffington's, Inc.
Phenobarbital and Atropine No.1	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore
Phenobarbital and Atrophine No.2	Tablet: Phenobarbital, 8 mg.; atrophine sulfate, 0.65 mg.	Do.
Phenobarbital and Atropine Tablets	Tablet: Phenobarbital, 8 mg.; atropine sulfate 1/1000 gr.	P.J. Noyes Co.
Do.	Tablet: Phenobarbital, 16 mg.; Atropine sulfate, 1/300 gr.	Do.
Phenobarbital and Atropine Tablets No.2	Tablet: Phenobarbital,¼ gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and Atropine Tablets No.3	Tablet: Phenobarbital,½ gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and belladonna	Tablet: Phenobarbital ¼ gr.; belladonna leaves, ½ gr. (total alkaloids 0.0015 gr.)	The Vale Chemical Co., Inc
Do.	Tablet: Phenobarbital, ½ gr.; belladonna extract, ½ gr.	Paine Drug Co.
Do.	Tablet: Phenobarbital, 16 mg.; belladonna extract 8 mg.	Eli Lilly and Co.
Phenobarbital and Belladonna No. 2	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ½ gr. (alkaloids 0.00156 gr.)	The Upjohn Co.
Phenobarbital with mannitol hexanitrate	Tablet: Phenobarbital, 7.5 mg.; mannitol hexanitrate 15 mg.; ascorbic acid power, 25 mg.; rutin, 25 mg.	Paul B. Elder Co., Inc (Harold M. Harter, D.V.M.)
Phenobarbital and mannitol hexanitrate	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	Meyer Drug and Surgical Supply Co.
Phenobarbitol Sodium Atropine No.1	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 mg.	McNeil Laboratories, Inc.
Phenobarbital Sodium Atropine No.2	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 mg.	McNeil Laboratories, Inc.
Phenobarbital Sodium Atropine No.3	Tablet: Phenobarbital Sodium, 20 mg.; atropine sulfate, 200 mg.	Do.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital and Sodium Nitrite	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	P.J. Noyes Co.
Phenobarbital Theocalcin	Tablet: Phenobarbital, 15 mg.: theobromine calcium salicylate, 0.5 gm	Knoll Pharmaceutical Co.
Phenodonna Tablets	Tablet: Phenobarbital, ¼ gr.; tincture belladonna 6 minims.	Flint Medical & Surgical Supply Co.
Phenodrox	Tablet: Phenobarbital, ¼ gr: atropine sulfate, 1/300 gr. magnesium trisilicate, 4 gr.; aluminum hydroxide gel. dried, 4 gr.	North American Pharmacal Inc.
Phyldrox	Tablet: Phenobarbital, 15 mg.; neothyline, 1000 mg.; ephedrine sulfate, 25 mg.	Lemmon Pharmacal Co.
Piptal PHB Elixir	Elixir (5 cc.) Phenobarbital 16 mg.; pipenzolate bromide, 5 mg.	Lakeside Laboratories, Inc.
Piptal PHB Tablets	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Prantal with Phenobarbital	Tablet: Phenobarbital, 16 mg.; diphemanyl methylsulfate, 100 mg.	Schering Corp.
Premarin with Phenobarbital	Tablet: Phenobarbital, 32 mg.; conjugated estrogens-equine, 0.625 mg.	Ayerst Laboratories.
Probanthine with phenobarbital.	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	G.D. Scarle & Co.
Probital	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	Do.
Propenite	Tablet: Phenobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	The Zemmer Co.
Prydonnal Spansule	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg.; scopolamine hydrobromide, 0.035 mg.)	Smith Kline & French Laboratories.
Quadrinal	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride 24 mg.; theophylline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Knoll Pharmaceutical Co.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Do	Suspension (5 cc.) Phenobarbital, 12 mg. ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate 65 mg.; potassium iodide, 160 mg.	Do.
Quintrate with Nitroglycerin and Phenobarbital.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate. 20 mg.; nitroglycerin. 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Board).
Quintrate with Phenobarbital	Tablet: Phenobarbital 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Do.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Robinul-PH	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A.H. Robins Co., Inc.
Robinul-PH Forts	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Ruhexatal	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; ascorbic acid, 10 mg.; rutin 20 mg.	Lemmon Pharmacal Co.
Rutol	Tablet: Phenobarbital, 8.0 mg.; mannitol hexanitrate, 16 mg.; rutin, 10 mg.	Pitman-Moore.
Salisil with Phenobarbital	Tablet: Phenobarbital, ¼ gr; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.
Salbella	Tablet: Phenobarbital, 1/8 gr.; aluminum hydroxide, 5 gr.; belladonna extract, 1/8 gr.	Wyeth Laboratories.
Sed-Tens	Tablet: (12 hr.): Amobarbital , 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena	Tablet: Butbarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids 0.20 mg.)	Plough Laboratories, Inc.
Sodium nitrite with Phenobarbital.	Tablet: Phenobarbital sodium, 1/8 gr.; sodium nitrate, 1 gr.; sodium bicarbonate, 2gr.; hawthorn berries, fluid extract, ¼ minim.	Paine Drug Co.
Do	Tablet: Phenobarbital, ½ gr.; sodium nitrate, 1gr.	Buffalo Pharmaceutical Supply Corp.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Spasticol PB	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceutical, Inc.
Spastosed	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 277 mg.: magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.
Synirin	Tablet: Phenobarbital, 8 mg.; aspirin, 324 mg.	Wm. P. Poythress & Co. Inc.
TCS	Tablet: Phenobarbital, 16 mg.; theobromine salicylate, 0.4 gm.; calcium salicylate, 0.06 gm.	Do.
Tedral-25	Tablet: Butabarbital 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A.	Tablet: Phenobarbital, 25 mg.; theophylline, 180 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tensodin	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 200 mg.	Knoll Pharmaceutical Co.
Tensophen	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P.J. Noyes Co.
Thedrizem	Tablet: Phenobarbital, 8 mg.; theophylline, hydrous, 100 mg.; ephedrine hydrochloride, 25 mg.	The Zemmer Co.
Theobarb	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Chemical Works.
Theobarb-R	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb Special	Tablet: Phenobarbital, 16 mg.; Theobromine, 325 mg.	Do.
Theobromine and Phenobarbital	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	P.J. Noyes Co.
Theobromine-Phenobarbital	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The S.E. Massengill Co.
Do	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	The Upjohn Co.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Theobromine-Phenobarbital Compound	Tablet: Phenobarbital, ¼ gr.; theobromine, and 2½ gr.; potassium iodide, 2½ gr.; potassium bircarbonate, 2 gr.	Do.
Theobromine with Phenobarbital No.1	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's, Inc.
Theobromine and sodium acetate with phenobarbital.	Tablet: Phenobarbital, ¼ gr.; theobromine and sodium acetate, 3 gr.	Paul B Elder Co., Inc.
Theobromine sodium salicylate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theocardone No. 2	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Do.
Theodide	Tablet: Phenobarbital, ¼ gr.; potassium iodide, 2½ gr.; theobromine sodium salicylate, 2½ gr.	The Vale Chemical Co., Inc.
Theoglycinate with Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with Racephedrine and Phenobarbital	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Do.
Theoplaphen	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 gm.	The S.E. Massengill Co.
Theominal	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M	Tablet: Phenobarbital, 15 mg.; theobromine, 320 mg.	Do.
Theominal R S	Tablet: Phenobarbital, 10 mg.; theobromine, 320 mg.; alseroxylon 1.5 mg.	Do.
Theophen	Tablet: Phenobarbital, ¼ gr.; theobromine sodium salicylate, 5 gr.; calcuim carbonate, 2½ gr.	The Vale Chmical Co.
Theorate	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
Thymodyne	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	P.J. Noyes Co.
Trocinate with Phenobarbital	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Wm. P. Poythress & Co., Inc.
Tricoloid	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	Burroughs Wellcome & Co.
Triophen	Tablet: Phenobarbital, ⅛ gr.; antropine sulfate 1/300 gr.; magnesium trisilicate, 7 gr.	The Vale Chemical Co.
Valpin P-B	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Endo Laboratories, Inc.
Vasorutin	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Buffington's, Inc.
Veralzem	Tablet: Phenobarbital 15 mg.; veratrum viride, 50 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Veratrite	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	Neisler Laboratories, Inc.
Veritag	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	S.J. Tutag and Co.
Vertegus	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¾ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	Burt Krone Co.
Veruphen	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Viritin	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
W.T.	Powder (4 gm.) Phenobarbital, 15 mg.; belladonna extract 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Warren-Teed Pharmaceuticals Inc.
W.T.	Tablet: Phenobarbital, 1/16 gr.; belladonna extract, 1/24 gr.; benzocaine, 1/16 gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3 ¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1%.	Do.
Xaniophen	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	Pitman-Moore
Zallogen Compound	Tablet: Phenobarbital, 8 mg.; tocamphyl, 75 mg.; homatropine methylbromide, 2.5 mg.	The S.E. Massengill Co.
Zantrate	Tablet: Cyclopentenylallylbarbituric acid ½ gr.; ephedrine sulfate, ½gr.; theophylline anhydrous, 2 gr.	The Upjohn Co.
Zem-Dab	Tablet: Butabarbital sodium, 10 mg.; dehydrocholic acid,60 mg.; ox bile dessicated, 120 mg.; homatropine methylbromide, 2.5 mg	The Zemmer Co.
No.23	Tablet: Phenobarbital, ½ gr.; aminophylline 3 gr.	Stayner Corp.
No.35	Tablet: Phenobarbital, ½ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, ½ gr.	Do.
No.36	Tablet: Pentabarbital sodium, ¼ gr.; ephedrine sulfate, ½ gr.; aminophylline, 3 gr.	Do.
No.65	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No.66	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No.75	Tablet: Phenobarbital, ¼ gr.; belladonna, ¼ gr.	Bariatric Corp.

701.002: continued

Trade name or other designation	Composition	Manufacturer or supplier
No.88	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No.89	Tablet: Phenobarbital ½ gr.; aminophylline, 1.5 gr.	Do.
No.111	Tablet: Phenobarbital, ½ gr.; ephedrine sulfate ¼ gr.	Do.
No.136	Tablet: Phenobarbital, 20 mg.; homatropine methylbromide, 5 mg.	Do.
No.643	Tablet: Phenobarbital, ½ gr.; theophylline, 2 gr.; ephedrine hydrochloride, ½ gr.	Do.
Rx.No.4104	Tablet: Phenobarbital, ½ gr.; calcium carbonate,7½ gr.; magnesium oxide, 4 gr.; atropine sulfate 1/200 gr.	The Zammer Co.
Rx.No.4105	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, 1/200 gr.	Do.
Rx.No 4108	Capsule: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 6½ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx.No.4123	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna, ¼ gr.	Do.
Rx.No.4126	Capsule: Pentobarbital sodium, 15 mg.; extract belladonna, 10 mg.	The Zemmer Co.
Rx.No.4143	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx.No.4152	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Rx.No.4155	Tablet: Phenobarbital, ¼ gr. ; atropine sulfate, 1/1000 gr.; aluminum hydroxide, 3¼ gr.; kaolin 3¼ gr.	Do.
Rx.No.4170	Tablet: Phenobarbital, ½ gr.; atropine sulfate 1/200 gr.; calcium carbonate, 10 gr.	Do.
Rx.No.4184	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

701.002: continued

(B) A controlled substance in Schedule V may be dispensed by a pharmacist without a prescription to a purchaser at retail provided that:

(1) The compound, mixture or preparation containing the controlled substance is not a prescription drug and,

(2) The compound, mixture, or preparation contains not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(C) Substances Excepted from Schedule V are subject to the following conditions:

(1) That such preparation shall be dispensed or sold in good faith as a medicine and not for the purpose of evading the provisions of the controlled substance law; and

(2) That the purchaser of such preparation identify himself to the satisfaction of the pharmacist; and

(3) That no more than four ounces of such preparation are dispensed or sold to a person during any 48 hour period, and

(4) That the pharmacist dispensing such excepted substances shall keep an accurate record book including the name and address of the purchaser, the name of the preparation, the strength per dosage unit, the quantity dispensed and the date.

701.003: Emergency Situations in Which Controlled Substances in Schedule II May Be Dispensed upon Oral Prescription

(A) "Emergency situations", for the purpose of permitting the dispensing of any controlled substance in Schedule II upon oral prescription, means those situations in which the practitioner who proposes to prescribe a controlled substance in Schedule II determines:

(1) That the immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user, and

(2) That no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II, and

(3) That it is not reasonably possible for the practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing.

(B) In case of an emergency situation as defined above, a pharmacist may dispense a controlled substance in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period; and

(2) The prescription is immediately reduced to writing by the pharmacist and contains all information required in M.G.L. c. 94C, § 20(a), except for the signature of the prescribing individual practitioner; and

(3) If the prescribing individual practitioner is not known to the pharmacist, he makes reasonable good faith effort to determine that the oral authorization came from a registered individual practitioner, including a callback to the prescribing individual practitioner using his phone number listed in the telephone directory or other good faith efforts to insure his identity.

(C) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of M.G.L. c. 94C, § 20(a), the prescription shall have written on its face "Authorization for Emergency Dispensing". The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period.

701.003: continued

(D) Upon receipt of the written prescription the dispensing pharmacist shall attach the prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Bureau of Narcotics and Dangerous Drugs, U.S. Department of Justice and the Commissioner of Public Health if the prescribing individual practitioner fails to deliver a written prescription to him within seven days.

REGULATORY AUTHORITY

105 CMR 701.000: M.G.L. c. 94C, § 4.

(105 CMR 702.000 THROUGH 719.000: RESERVED)

(PAGES 4033 THROUGH 4100 ARE RESERVED FOR FUTURE USE.)

105 CMR 721.000: STANDARDS FOR APPROVED PRESCRIPTION FORMS IN MASSACHUSETTS

Section

721.001: Purpose
721.002: Authority
721.003: Citation
721.010: Scope and Application
721.020: Definitions
721.000: Prescriptions Forms
721.031: Additional Medicaid Requirement
721.032: Approved Prescription Forms
721.033: Invalid Prescriptions
721.035: Prescribing More than One Product
721.041: Effective Date

721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for prescription forms approved by the Department of Public Health for use by practitioners in Massachusetts.

721.002: Authority

105 CMR 721.000 is adopted pursuant to M.G.L. c. 30A, § 2, c. 94C, § 6, c. 111, § 3, c. 112, § 12D, and St. 1976, c. 470, § 3.

721.003: Citation

105 CMR 721.000 shall be known as 105 CMR 721.000: *Standards for Approved Prescription Forms in Massachusetts.*

721.010: Scope and Application

105 CMR 721.000 establishes the standards which all prescription forms written by practitioners in the Commonwealth must meet in order to be approved by the Department of Public Health as required by M.G.L. c. 112, § 12D.

721.020: Definitions

The terms used herein shall have the meanings set forth below. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1 and not defined herein shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Department means the Department of Public Health established pursuant to M.G.L. c. 17, § 3.

Drug Product means a drug produced by a specific company, whether under a brand name or under a generic name.

Interchangeable drug product means a product containing a drug in the same amounts of the same active ingredients in the same dosage form as other products with the same generic or chemical name.

Practitioner means a physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered pursuant to M.G.L. c. 94C to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice in the Commonwealth.

721.030: Prescription Forms

(A) Every prescription written in the Commonwealth must be on a prescription form which conforms to the requirements set forth under 105 CMR 721.030(A)(1) and (2) and (3):

(1) The prescription form shall contain a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his/her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his/her name, there shall be a space of at least ½ inch and no more than one inch in which the practitioner may write in his/her own handwriting the words "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner writes the words 'no substitution' in this space". No other form or procedure, including initialing, checking, initialing a box, pre-printing or stamping a prescription form shall be deemed by the pharmacist to be the equivalent of the practitioner's handwritten statement "no substitution".

(2) The name and address of the practitioner shall be clearly printed or typed on the form. A hospital or clinic prescription form shall have the name and address of the hospital or clinic clearly printed or typed on the form.

(3) The prescription form shall contain space for the practitioner to enter clearly the following information:

(a) the registration number of the practitioner;

(b) date of issuance of the prescription;

(c) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;

(d) name and address of the patient, except in a veterinary prescription;

(e) directions for use, including any cautionary statements required, and

(f) a statement indicating the number of times to be refilled.

(4) Prescription forms for certified nurse midwifes, nurse practitioners, psychiatric nurses and physician assistants shall also contain space for the nurse or physician assistant to enter clearly the name of the supervising physician.

721.031: Additional Medicaid Requirement

(A) Practitioners who write prescriptions for Medicaid recipients are advised that for each multiple source drug designated by the Pharmaceutical Reimbursement Board of the United States Department of Health, Education and Welfare, and published in the *Federal Register*, reimbursable cost under the Medicaid program is limited to the lower of the the maximum allowable cost (MAC) established by the Board or the estimated acquisition cost set by the Rate Setting Commission. (42 C.F.R. 450.30(b)(2)(i)(b)(ii) and 106 CMR 406.421)

(B) Practitioners are further advised that under the above-cited regulations, reimbursement for the drug product dispensed may not exceed the limits described in 105 CMR 721.031(A) unless the practitioner writes the words "no substitution" in his/her own handwriting in the space provided below the signature line in addition to signing the signature line. If the practitioner indicates interchange by signing the signature line and not writing the words "no substitution" in his/her own handwriting in the space provided below the signature line, no additional handwritten notation is required.

721.032: Approved Prescription Forms

The following is an example of a signature line format which conforms to 105 CMR 721.030(B) and is approved by the Department for use by practitioners in Massachusetts (Exhibit 1).

Exhibit I

In accordance with 105 CMR 721.030(B), the following is an illustration of the Department of Public Health approved signature line format.

_____ M.D.

Interchange is mandated unless the practitioner writes the words "no substitution" in this space

721.033: Invalid Prescriptions

(A) A prescription on a form which does not conform to 105 CMR 721.000 is invalid and shall not be filled.

(B) A prescription on which the practitioner has failed to sign his/her name on the signature line is invalid and shall not be filled.

721.035: Prescribing More Then One Drug Product

Practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate approved prescription form. More than one drug product may be prescribed in the hospital setting for the treatment of those disease entities specified on a list established by the Department; provided, however, that the format of the form is sufficient to permit clear directions for use and interchange.

721.041: Effective Date

Effective November 1, 1986, prescriptions will be valid only if written on DPH approved one-signature line prescription forms.

REGULATORY AUTHORITY

105 CMR 721.000: M.G.L. c. 94C, § 6; c. 111, § 3; c. 112, § 12D; St. 1976, c. 470, § 3.

NON-TEXT PAGE

105 CMR 722.000: DISPENSING PROCEDURES FOR PHARMACISTS

Section

722.001: Purpose
722.002: Citation
722.010: Scope and Application
722.020: Definitions
722.040: Medical Emergencies
722.050: Oral Prescriptions
722.060: Generic Prescriptions
722.070: Labelling
722.080: Out-Patient Pharmacies
722.090: Hospital Pharmacies

Dispensing Procedures
722.100: Severability

722.001: Purpose

The purpose of 105 CMR 722.001 is to describe procedures which pharmacists must follow when dispensing drug products in accordance with St. 1976, c. 470 and the regulations promulgated thereunder.

722.002: Citation

105 CMR 722.000 shall be known as 105 CMR 722.000: *Dispensing Procedures for Pharmacists.*

722.010: Scope and Application

105 CMR 722.000 establishes the rules and regulations which a pharmacist must follow to be in accordance with St. 1976, c. 470, when dispensing drug products.

722.020: Definitons

The terms used herein shall have the meaning set forth below. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1, and not defined herein shall have the meanings set forth therein when used in 105 CMR 722.000, unless the context clearly requires a different interpretation.

Discharge Patient. For the purpose of 105 CMR 722.000 only, a discharge patient is a person who has been released from an inpatient hospital bed and is no longer registered as a hospital patient.

Drug Product means a product which contains an active drug ingredient and is in a dosage form *e.g.* tablet, capsule, or solution, generally, but not necessarily in combination with other substances included in the manufacturing process. An active drug ingredient is that portion of drug product intended to produce a therapeutic effect.

Drug Purchaser means any individual or third-party payor purchasing prescribed drugs on behalf of himself or others.

Emergency Room Patient. For the purposes of 105 CMR 722.000 only, an emergency room patient is a person registered at a hospital for the purpose of receiving emergency services or treatment and who departs from the hospital immediately after receiving such emergency services or treatment.

Generic Name means a non-proprietary (common) name used to identify a drug product as listed by the United States Adopted Names Council and the United States Pharmacopeia in the *USAN/USP Dictionary of Drug Names.*

722.020: continued

Hospital Employees. Employees of the hospital shall include persons currently on the payroll of the hospital and their spouse and dependents living in the same household, medical staff members, volunteers, students and/or individuals contracted for employment by the hospital.

Hospital Inpatient. For the purposes of 105 CMR 722.000 only, a hospital inpatient is a person formally admitted to a hospital bed for the purpose of receiving services or treatment and who remains in the hospital at least overnight. A person is considered a hospital inpatient if, after formal admission as an inpatient, such person is later discharged for medical reason or is transferred to another hospital before such person has occasion to occupy a hospital bed overnight.

Hospital Outpatient. For the purposes of 105 CMR 722.000 only, a hospital outpatient is a person formally registered on the hospital records as an outpatient and who is currently receiving services or treatments at a clinic of the hospital (*e.g.*, asthma clinic, arthritis clinic, radiation therapy clinic, *etc.*). Patients who are seen at a doctor's private office within or without the hospital shall not be deemed to be hospital outpatients.

Hospital Pharmacy means a hospital's central, satellite or branch pharmacy.

Hospital Premises means, for the purposes of 105 CMR 722.000 only, the buildings and contiguous grounds of a hospital.

Hospital-based Skilled Nursing Facility means, for the purposes of 105 CMR 722.000 only, a long-term care facility or unit thereof that is an integral and subordinate part of the hospital, is operated with other departments of the hospital under common governance and professional supervision such that the skilled nursing facility and the hospital are subject to the bylaws and operating decisions of a common governing board, is fully integrated with all other services of the hospital, and is financially integrated with the hospital.

Interchange means the exchange of a less expensive reasonably available drug product selected from the *Massachusetts List of Interchangeable Drugs* for a prescribed brand name drug product.

Interchangeable Drug Product means a product containing a drug in the same amounts of the same active ingredients in the same dosage form as other drug products with the same generic or chemical name.

Less Expensive means that the charge to the drug purchaser in the pharmacy where the sale takes place must be less for the interchanged drug product, whether brand name or generic, than the selling price for the prescribed drug product on the day of purchase.

Medical Emergency is a situation which requires immediate drug therapy for a patient in order to alleviate severe pain or avert disability or loss of life.

Pharmacist means any pharmacist registered in the Commonwealth to dispense controlled substances, and including any other person authorized to dispense controlled substances under the supervision of a pharmacist registered in the Commonwealth. Any pharmacist who fills a prescription is responsible for complying with all requirements of M.G.L. c. 112, § 12D, 105 CMR 720.000 *et seq.*, 721.000 *et seq.*, 722.000 *et seq.*, and all subsequent amendments whether or not that pharmacist orders drugs for the pharmacy.

Reasonably Available Drug Product means any interchangeable drug product which appears on the *Massachusetts List of Interchangeable Drugs* as long as that product is sold through interstate commerce and is obtainable by a pharmacist within a time period of 72 hours or less.

722.040: Medical Emergencies

In a medical emergency the pharmacist may fill a prescription marked "no substitution" by dispensing a less expensive interchangeable drug product as allowed by the *Massachusetts List of Interchangeable Drugs* if the particular brand is not in stock; similarly, the pharmacist may fill a prescription not marked "no substitution" in a medical emergency by dispensing the brand name product as written if he has no less expensive interchangeable drug product in stock to be dispensed.

In such instances, the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and the person purchasing the drug product must indicate acceptance of this deviation from the law by legibly writing his or her signature on the prescription. All such prescriptions shall be clearly identifiable and available for review by officials enpowered to enforce the laws of the Commonwealth.

722.050: Oral Prescriptions

Upon receiving an oral prescription for a brand name drug product, a pharmacist shall in addition to the information the pharmacist now requests, ascertain whether or not the prescriber wishes "no substitution" to be marked on the prescription and record this information with all other required information on his/her prescription log.

722.060: Generic Prescriptions

Upon receiving a prescription for a generic name drug product with no manufacturer specified by the prescriber, the pharmacist may select, regardless of whether or not the prescriber has marked "no substitution" on the prescription, any legally marketed drug product whether or not it appears in the *Massachusetts List of Interchangeable Drugs*, in accordance with the prescriber's intent and the normal exercise of professional judgement.

722.070: Labelling

(A) When a less expensive generic drug product has been dispensed, the words "interchange" plus the generic name and manufacturer of the product shall appear on the label in the following manner:

"Interchange": (Generic name of less expensive drug product dispensed plus manufacturer)

(B) When a less expensive brand name drug product has been dispensed, the words "interchange" plus either the generic name and manufacturer of the product or the less expensive brand name dispensed shall appear on the label in the following manner:

"Interchange": (generic name of less expensive brand drug product plus manufacturer *of* brand name of less expensive drug product)

(C) In addition to the above, the brand name of the prescribed drug product may also appear on the label in the following manner:

"Interchange": (Name of less expensive generic drug product plus manufacturer or brand name drug product actually dispensed) *for* (brand name drug product prescribed)

(D) Abbreviations are permissible as long as they are understandable, *e.g.*, "IC" may be used for "Interchange" and manufacturer's names may be abbreviated as shown in the *Massachusetts List of Interchangeable Drugs*.

722.080: Out-Patient Pharmacies

A pharmacist employed by a health care facility as defined in 105 CMR 700.001, other than a hospital, and who provides outpatient pharmacy services must comply with M.G.L. c. 112, § 12D and regulations promulgated thereunder when filling prescriptions. In particular, no prescription shall be accepted as valid by such a pharmacist unless it is on a prescription form approved by the Department pursuant to M.G.L. c. 112, § 12D.

722.090: Hospital Pharmacies

(A) Hospital pharmacies may fill medication orders for hospital inpatients, prescriptions for hospital outpatients and employees, and medication orders or prescriptions for inpatients of a hospital-based skilled nursing facility or a long-term care facility that is solely owned by a hospital that meets the Federal criteria for a sole community hospital contained at 42 CFR § 412.92 and is located on the hospital premises. Patients of such a hospital-based skilled nursing facility or long-term care facility shall be considered hospital patients for the purposes of receiving pharmacy services.

(B) Notwithstanding the provisions of 105 CMR 722.090(A), hospital pharmacies and their satellites or branches may fill prescriptions for emergency room patients and discharge patients in an amount not to exceed a 14 day supply of the prescribed medication.

(1) Prescriptions for emergency room patients and discharge patients may not be refilled by the hospital pharmacy.

(2) Drug products which are only available from the manufacturer in greater than fourteen day supplies may be dispensed in larger quantities for emergency room and discharge patients. The quantity dispensed, however, may not exceed the smallest quantity supplied by the manufacturer.

(C) Notwithstanding 105 CMR 722.090(B), in the case of rare and unusual drugs which generally are not available in a retail pharmacy, a hospital pharmacist may fill prescriptions for emergency room patients and discharge patients in the amount prescribed by the practitioner. The Department may establish a list of those drugs which may be obtained from a hospital pharmacy under 105 CMR 722.090(B).

(D) In filling prescriptions in accordance with 105 CMR 722.090(A), (B) and (C), no prescription shall be accepted as valid by a pharmacist unless it is on a prescription form approved by the Department pursuant to M.G.L. c. 112, § 12D.

(E) Whenever a practitioner indicates "no substitution" on a prescription form, a hospital pharmacy shall dispense the drug product prescribed by the practitioner. Whenever a practitioner does not indicate "no substitution" on a prescription form, a hospital pharmacy shall dispense a less expensive drug product as listed in the hospital's formulary. A drug listed on the hospital's formulary shall be presumed to be a less expensive drug product. The hospital's formulary is a continually revised compilation of pharmaceuticals to be dispensed in the hospital as determined by the medical staff of the hospital. The hospital formulary shall include only those drugs which have been found to be therapeutically equivalent by the federal Food and Drug Administration.

722.100: Severability

The provisions of 105 CMR 722.000 are severable. If any provision shall be declared invalid by any court, such provision shall be null and void and such determination shall not affect or impair any of the remaining provisions.

REGULATORY AUTHORITY

105 CMR 722.000: M.G.L. c. 94, § 6; c. 112, § 12.

(105 CMR 723.000: RESERVED)

NON-TEXT PAGE

105 CMR 724.000: IMPLEMENTATION OF M.G.L. c. 94D: THE CONTROLLED SUBSTANCES THERAPEUTIC RESEARCH ACT

Section

724.001: Purpose and Scope
724.002: Definitions
724.003: Requirements for the Therapeutic Research Program
724.004: Certification of Patients for Eligibility in the Therapeutic Research Program
724.005: Certification and Review of Patients for Participation in the Therapeutic Research Program
724.006: Guidelines
724.006: Severability

724.001: Purpose and Scope

(A) The purpose of 105 CMR 724.000 is to set forth the requirements for the therapeutic research program in M.G. L. c. 94D.

(B) 105 CMR 724.000 establishes standards and criteria for a therapeutic research program to conduct research and monitor experimentation in the use of marijuana as a therapeutic modality for patients certified to participate in the program.

724.002: Definitions

For the purpose of 105 CMR 724.000, the following definitions apply unless the context or subject matter requires a different meaning.

Commissioner means the Commissioner of Public Health.

Department means the Department of Public Health.

Marijuana means the plant *Cannabis sativa L.*, tetrahydrocannabinol, or a chemical derivative or synthesis of tetrahydrocannabinol.

Patient means a person who has been certified by a physician as eligible for the therapeutic research program in accordance with the provisions of 105 CMR 724.000.

Physician means a person licensed in accordance with the provisions of M.G.L. c. 112, § 2.

Program means the therapeutic research program approved by the Department to conduct research and monitor experimentation in the use of marijuana as a therapeutic modality in alleviating the nausea and ill-effects of cancer chemotherapy and radiation therapy, in decreasing intraocular pressure in patients with glaucoma, and in decreasing airway resistance in patients with asthma.

724.003: Requirements for the Therapeutic Research Program

(A) Patient Eligibility. Eligibility for the therapeutic research program shall be limited to patients who experience the nausea and ill-effects of cancer chemotherapy and radiation therapy; glaucoma patients who experience intraocular pressure from glaucoma; and patients with asthma who experience severe respiratory problems or discomfort.

(B) Supply. The Department shall contract with the National Institute on Drug Abuse, the National Cancer Institute or other manufacturer, distributor or analytical laboratory for the receipt of a supply of analyzed marijuana in accordance with all applicable state and federal laws.

(C) Approval of Institutional Review Board. Prior to the implementation of any study protocol pursuant to the therapeutic research program, the protocol shall undergo the review and approval of an Institutional Review Board in accordance with the provisions of 45 CFR part 46 and 21 CFR part 56, as most recently amended.

724.002: continued

(D) Location of Use. A patient may not use the marijuana provided by the program in the presence of persons under the age of 18, in a moving vehicle, or in a public place, or in any manner inconsistent with the requirements of the program.

(E) Record-Keeping. The therapeutic research program established pursuant to 105 CMR 724.000 shall meet all record-keeping requirements of 21 CFR part 312, as most recently amended.

(F) Reporting.

(1) The Department shall file an annual report of the activities of the program with the Governor and General Court.

(2) The therapeutic research program shall meet all the reporting requirements found in 21 CFR part 312 and 105 CMR 700.009, as most recently amended.

724.004: Certification of Patients for Eligibility in the Therapeutic Research Program

(A) A physician may certify the following types of patients for eligibility to participate in the program:

(1) patients who experience the nausea and ill-effects of cancer chemotherapy and radiation therapy;

(2) glaucoma patients who require the decreasing of intraocular pressure; and

(3) patients with asthma who require the decreasing of airway resistance.

(B) Prior to the participation of a patient in the program, a physician must certify that a patient is eligible for the program by providing the Department with the following information:

(1) that the patient is threatened by loss of life or sight; or, for patients with asthma, that the patient experiences severe respiratory problems or discomfort;

(2) that the patient is not responding to or has incurred severe side effects from the administration of conventional controlled substances;

(3) that the administration of marijuana may have beneficial therapeutic effects upon the patient; and,

(4) that the patient has given in writing his or her informed consent based upon information about the nature, duration, and purpose of the research, the method and means by which it is to be conducted, the inconveniences and hazards reasonably to be expected, and the effects upon the patient's health or person which may reasonably be expected to come from his or her participation.

(C) A physician who intends to certify a patient for eligibility to participate in the program shall obtain the written informed consent of said patient on a form provided by the Department.

(D) A physician who certifies a patient for eligibility to participate in the program shall submit the criteria for such patient's eligibility to the Department on the certification form provided by the Department.

(E) The Department may request additional information from a physician who certifies a patient for eligibility to participate in the program if it deems it necessary.

724.005: Certification and Review of Patients for Participation in the Therapeutic Research Program

(A) The Department shall convene a panel of three physicians appointed by the Commissioner for the purpose of reviewing all certification forms submitted by physicians to the Department for compliance with 105 CMR 724.000

(B) The panel shall conduct a timely review and inform the physician who submitted the certification form of its decision to approve or deny certification of the patient's participation in the program.

(C) All certification forms shall be kept on file at the Department and a copy included in the patient's medical record.

724.005: continued

(D) The records of the Department which are maintained pursuant to the therapeutic research program shall not be deemed to be public records within the meaning of M.G.L. c. 4, § 7.

724.006: Guidelines

(A) The Department shall establish guidelines for the therapeutic research program which shall include, but not be limited to, the criteria for submission of study protocols and the criteria for patient participation in a study protocol.

(B) The Department shall have oversight over any study protocol which is instituted pursuant to 105 CMR 724.000.

724.007: Severability

The provisions of 105 CMR 724.000 are severable. If any provision herein is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

REGULATORY AUTHORITY:

105 CMR 724.000: M.G.L. c. 94C, § 34; c. 94D.

NON-TEXT PAGE

(105 CMR 725.000 through 729.000: RESERVED)

(PAGES 4149 THROUGH 4160 ARE RESERVED FOR FUTURE USE.)

105 CMR 730.000: THE DISTRIBUTION OF BIOLOGIC PRODUCTS

(A) Subjects to the provisions of 105 CMR 730.000, boards of health in cities and towns are the responsible agencies in their respective communities for procurement, proper storage and issue of biologic products used in the control of diseases dangerous to the public health.

(B) Biologic distribution stations shall be established by local boards of health in cities and towns of 10,000 population or over.

(C) Cities and towns of less than 10,000 population may establish biologic distribution stations, when the need has been established, subject to the approval of the Department.

(D) A board of health not equipped to act as a distribution station may designate a hospital or drug store as its agent, but may not designate more than one agency.

(E) A board of health may maintain more than one distribution station but products will be delivered by the Department to only one agency in each town or city, except when needed for emergency use.

(F) Distribution stations must be under the charge of a qualified person, familiar with the principles of care and handling of biologic products, and must supply and use adequate refrigerating facilities. They must observe such special requirements for the storage, handling or issue of products, as may from time to time be communicated to them by the Department or its agents.

(G) The location, responsible personnel, equipment and operation of all distribution stations are subjected to the approval of the Department. Biologic stations may be discontinued by the Department when the need no longer exists and/or when the products are being improperly stored, handled, or distributed.

(H) District health officers or their authorized representatives will inspect biologic products on hand at distribution stations at least once a year, and their findings will be reported to the Superintendent, Institute of Laboratories.

(I) The delivery of diphtheria and scarlet fever antitoxins, smallpox vaccine, typhoid-paratyphoid vaccine, Schick outfits, diphtheria toxoid, tuberculin, immune serum globulin, silver nitrate solution, and such other products as the Superintendent, Institute of Laboratories may designate is limited to boards of health, except as noted below.

(J) Biologic products as specified in 105 CMR 730.000(I) may be delivered directly to physicians or hospitals located in cities or towns of less than 10,000 population which do not maintain a biologic station.

(K) Distribution of citrated whole blood, normal human plasma, or their fractions (except immune serum globulin) is limited to physicians, hospitals or their qualified agents. These products must be obtained by calling at the laboratory except when their shipment is authorized by the Superintendent, Institute of Laboratories.

(L) Physicians, hospitals, boards of health, and other responsible agencies, or their qualified agents, may obtain all biologic products by calling at the laboratory, subject to the provisions noted below.

(M) Any product, or any part of a specific request for products, may, where adequate cause exists, be withheld from delivery or distribution, upon the decision of the Superintendent, Institute of Laboratories. The Superintendent may, for valid reasons, authorize exceptions to any of the regulations stated below.

REGULATORY AUTHORITY

105 CMR 730.000: M.G.L. c. 111, § 5.

NON-TEXT PAGE

105 CMR 731.000: THE SALE OF SURPLUS BIOLOGIC PRODUCTS

(A) As only "excess" products may be sold under statute, the decision as to what products shall be considered "excess" stock shall be made in all instances by the Department.

(B) Charges for such products shall be determined from time to time by the Department after a study by the fiscal office and the Institute of Laboratories.

(C) No one connected with the Institute of Laboratories shall be permitted to sell, exchange, or barter any biologic products belonging to the Commonwealth, except in accordance with the rules and regulations herein provided and the approval of the Superintendent of the Institute of Laboratories.

(D) Sales of products are to be made only when these products are to be used outside the Commonwealth of Massachusetts, and under no circumstances shall any charge be made for products intended for use within the Commonwealth.

(E) In the case of products sold no credit or rebate shall be issued for any products not used before the expiration date stamped on the label or for empty containers returned.

REGULATORY AUTHORITY

105 CMR 731.000: M.G.L. c. 111, § 5.

NON-TEXT PAGE

(105 CMR 732.000 through 749.000: RESERVED)

(PAGES 4167 THROUGH 4174 ARE RESERVED FOR FUTURE USE.)

105 CMR 750.000: LICENSING AND APPROVAL OF DRUG TREATMENT PROGRAMS

Section

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750.010: Scope of 105 CMR 750.000

105 CMR 750.000 sets forth the minimum standards for the operation of public and private drug treatment programs operating in the Commonwealth, regardless of their source of funding. The following specific modalities are covered by 105 CMR 750.000: residential drug treatment programs; ambulatory programs; including day treatment, and crisis intervention; and methadone treatment programs. Drug programs operated by the federal government are not regulated by 105 CMR 750.000.

750.020: Definitions

Administrator - means the person responsible for the operation of a drug treatment program.

Aftercare - means the provision of or the arrangement for counseling and/or supportive services to those clients who have successfully completed a residential treatment program but who require continued formal support.

Approval - means a certification, in writing, whether full or provisional, issued by the Department to a public agency or institution thereof which authorizes it to operate a drug treatment program.

Client - means a person applying for admission or admitted to a facility or program for treatment services.

Client Record - means any information regarding the identity, diagnosis, prognosis, or treatment of, or other program dealings with, any past or present program client.

Day Treatment Program - means a non-residential treatment program for persons able to reside in the community but who need the reinforcement of a structured environment in order to become and/or remain drug free.

Department - means the Department of Public Health.

Dependency Related Drug - means a controlled substance as defined in M.G.L. c. 94C, § 1.

Division - means the Division of Drug Rehabilitation, Department of Public Health.

Drug Treatment Program - means a program which provides therapeutic services and necessary supportive services especially designed for the treatment of drug dependent persons or persons in need of immediate assistance due to the use of a dependency-related drug.

Facility - means any public or private place, or portion thereof, which is not part of or located at a penal institution and which is not operated by the federal government, where especially-designed services are provided for the treatment of drug dependent persons or persons in need of immediate assistance due to the use of a dependency-related drug.

License - means a certification, in writing, whether full or provisional, issued by the Department to any responsible and suitable person which authorizes that person to operate a drug treatment program.

Licensee - means any person holding a license or approval from the Department to operate a drug treatment program.

Methadone Detoxification - means the withdrawal of a client from dependence on heroin or other opiate-like drugs by means of administering or dispensing methadone as a narcotic drug in decreasing dosages in accordance with Federal Food and Drug Administration regulations.

Methadone Maintenance - means the continued administering or dispensing of methadone in conformance with Federal Food and Drug Administration regulations, in conjunction with the provision of appropriate social and medical services, at relatively stable dosage levels as an oral substitute for heroin or other opiate-like drugs, for an individual dependent on heroin or other opiate-like drugs.

Methadone Treatment Program - means a drug treatment program which furnishes a comprehensive range of services using methadone for the detoxification and/or maintenance of narcotic dependent persons, conducting the initial evaluation of clients and providing on-going treatment at a specified location or locations.

Person - means an individual, corporation, government, governmental subdivision or agency, business trust, estate trust, partnership, association, or any other legal entity.

750.020: continued

Qualified Health Professional - means a person who by virtue of education, training, and experience is capable of assessing the psychological and/or sociological needs of drug abusers to determine the treatment plans most appropriate for clients in programs administering services.

Residential Drug-Free Program - means a program which provides long-term social and rehabilitative services to live-in clients who are unable to remain drug-free while residing in the community.

Staff Member - means an individual designated by the program to provide client treatment services on a regular basis.

Treatment - means the provision of services for the care and rehabilitation of drug dependent persons, or persons in need of immediate assistance due to the use of a dependency related drug, including, but not limited to, medical, psychiatric, psychological or other counseling services.

Treatment Plan - means a written plan concerning a client, including, but not limited to, short and long range goals, designation of a primary counselor, type and frequency of counseling services, dosage level and plan for change in dosage level, if any, including planned rate of detoxification and social, medical and support services as needed by the individual client.

750.030: Procedure for Issuing Licenses and Approvals

(A) Procedure for Issuing Licenses.

(1) Any person, other than a licensed general hospital or a department, agency, or institution of the federal government, the commonwealth or any political subdivision thereof, shall file an application for licensure with the Department for the establishment or operation of a drug treatment program. The application shall be on a form prescribed by the Department. Any person seeking to renew a license shall file an application for renewal in writing to the Department on a form prescribed by the Department not less than 30 days prior to the date of expiration of the current license.

(2) The applicant shall be the person or persons having complete responsibility for the administration and business of the program.

(3) Upon receipt and review (which may inlcude interviews, site-visits, and technical assistance related to licensing standards) of an application for a license or renewal thereof, and after consideration of the applicant's past performance, including: financial viability, absence of criminal activity, record of compliance with these or any previously applicable regulations under any past license, approval, or contract, the Department shall issue or renew a license if it finds that the applicant is in compliance and that it is responsible and suitable to establish and maintain a program.

(4) Before a license is issued, the applicant shall provide the following documents:

(a) a statement of the ownership of the facility, including the names and addresses of all owners, or in the case of corporations, the officers; in the case of a public program, the statutory basis of its existence;

(b) an up-to-date financial report of the program and in the case of a new program, evidence of its financial capability to operate for at least three months;

(c) a statement describing the program's personnel policies, where required under 105 CMR 750.330;

(d) written agreements with community operations or agencies for provision of emergency medical and mental health services;

(e) a certification by the local board of health or health department that the facility is in compliance with local and/or state ordinances regarding health, or a statement from the inspecting authority providing conditional approval and indication that the health of the clients would not be endangered in the facility;

(f) a certification by the Department of Public Safety or the appropriate local building inspector;

(g) a certification from the local zoning board that the facility is in compliance with applicable zoning regulation, where applicable; and

(h) evidence of ability to comply with 105 CMR 750.000.

750.030: continued

(5) Residential Treatment Programs shall indicate the maximum bed capacity they intend to maintain for the licensure period.

(6) A license or approval is valid for two years from the date of issuance.

(B) Procedure for Issuing Approvals.

(1) Any department, agency or institution of the Commonwealth or any political subdivision thereof, shall file an application for a certificate of approval with the Department for the establishment or operation of a drug treatment program.

(2) Applications for a certificate of approval shall be subject to all applicable requirements as stated in 105 CMR 750.030(A) and St. 1981, c. 704, § 7.

750.040: Provisional Licenses and Approvals

(A) When the Department finds that a current licensee or an applicant for licensure of a new program has not complied or is unable to comply with all applicable regulations but is in substantial compliance and has the capability of conforming to all regulations, the Department may issue a provisional license or approval provided that the care given by the program is adequate to protect the health and safety of the clients.

(B) A provisional license or approval is valid for a period not to exceed six months and may be renewed once for no more than six months.

750.050: Inspection

(A) The Department may at any time visit and inspect any program subject to licensure or approval by the Department, in order to determine whether such program is being operated in compliance with the law and 105 CMR 750.000.

(B) Failure to allow access of authorized department inspectors to the program shall be an adequate and independent ground for revocation of a license or approval.

750.060: Deficiency Correction Order

(A) Whenever the Department finds upon inspection or through information in its possession that a program is not in compliance with any applicable licensing regulations of the Department, the Department may order that the deficiency be corrected.

(B) Every such correction order shall be in writing and shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, and the provision(s) of law and regulation relied upon. The period shall be reasonable, and except when the Department finds an emergency dangerous to the health and safety of clients, not less than 30 days from receipt of such order.

750.070: Suspension, Revocation, and Refusal to Issue or Renew Licenses and Approvals

The Department may suspend, revoke, refuse to issue or refuse to renew a license or approval for cause. Cause shall include but not be limited to the following:

(A) The applicant or licensee failed to comply with any applicable regulation or any deficiency correction order;

(B) The applicant or licensee furnished or made misleading statements or report required under 105 CMR 750.000;

(C) The applicant or licensee refused to submit any reports or make available any records required under 105 CMR 750.000;

(D) The applicant or licensee refused to admit at a reasonable time any employee of the Department for purposes of investigation or inspection authorized by 105 CMR 750.000; or

750.070: continued

(E) There is a reasonable basis for the Department to conclude that there is a discrepancy between representations by a program as to the treatment services to be afforded clients and the treatment services actually rendered or to be rendered.

Whenever the Department commences an action pursuant to this section, it shall initiate an adjudicatory proceeding in accordance with the requirements of M.G.L. c. 30A. All such adjudicatory proceedings shall be conducted in accordance with 801 CMR 1.00: *Adjudicatory Rules of Practice and Procedure.*

750.080: Suspension in Emergency

(A) The Department may suspend any license or approval without a hearing if failure of the operator or licensee to comply with any applicable regulation results in a situation which endangers the life or safety of clients or staff of the program.

(B) Upon written request of an aggrieved party, a hearing, in accordance with M.G.L. c. 30A shall be held within 21 days of the effective date of the suspension.

750.090: Posting of License or Approval

Every licensee shall post in a conspicuous place the current license or approval issued by the Department.

750.100: Notification of Legal Proceeding

Every licensee shall report in writing to the Department any legal proceeding (within ten days of initiation of such proceeding) brought against it or any person employed by the program, if such proceeding arises out of circumstances related to the care of clients in the program or to the continued operation of the program.

750.110: Notification of Death

The licensee shall notify the Department and client's known next-of-kin as soon as possible and in writing not later than 72 hours of any client death occurring on program premises. In the case of drug dispensing programs, notification shall occur regardless of place of death.

750.120: Notification of Accident, Fire, and Communicable Disease

The licensee shall notify the Department as soon as possible and in writing no later than 72 hours of any communicable disease or accident requiring medical attention involving clients or program staff or any fire or accident resulting in damage to the facility.

750.130: Notification of Closure

(A) At least 90 days prior to the temporary discontinuance of operation of a program for any period, the licensee shall request permission from the Department and notify all clients of its intent. Discontinuance of service shall be treated as an abandonment of the license or approval thereof, except where the Department has granted permission in advance. Such permission shall be given only in exceptional circumstances and for no longer than required.

(B) At least 90 days prior to the permanent closure of a program, the licensee shall give written notice of such intent to the Department and to all clients. The licensee shall be responsible for appropriate placement of clients.

750.140: Change of Name, Ownership, or Location

(A) A license or approval shall not be transferable from one licensee to another, from one program to another, or from one facility to another.

750.140: continued

(B) The licensee shall provide prior notification, in writing, to the Department of any change in ownership of the program.

(C) The licensee shall provide notification, in writing, to the Department of any change in principal administrative or clinical personnel in the program.

(D) Prior to any change in location of the program or addition or reduction in the program capacity, the licensee shall notify the Department in writing.

750.150: Waiver

The Department may upon written request waive any provision contained in 105 CMR 750.700 through 750.720 if the applicant provides clear and convincing evidence, including at the request of the Department expert opinion, which demonstrates to the satisfaction of the Department that the applicant's alternative method will comply with the intent of the regulation for which the waiver is requested. The Department may consider any other evidence relevant to the request for waiver.

750.160: Information Required by the Department

(A) Upon request of the Department, each program shall make available to the Department any information and/or data required to be kept and maintained under 105 CMR 750.000 and any other information and/or data reasonably related to the evaluation of the program.

(B) In the event of any substantial change in program service capacity or treatment approach, whether an addition or deletion, or any substantial change in the physical plant affecting program capacity, the licensee shall give written notification of the intent to the Department (and to all clients directly affected) within a time which is reasonable to permit the Department to take any steps necessary to determine whether any change in licensure status is required, but in any event not less than 90 days prior to the proposed change.

750.300: Statement of Purpose

Each licensee shall adopt and maintain a current, written statement of purpose, identifying its goals, objectives, and philosophy. This statement shall be reviewed annually and modified, as necessary, as indicated by changes in the characteristics of the clients served, changes within the community where the facility is located, or any significant result of a program's self-evaluation.

750.310: Policy Manual

(A) Each licensee shall adopt and maintain a current policy manual containing clear and concise statements regarding:

(1) Types of services provided, the specific qualifications for service delivery staff, restrictive criteria for receipt of specific services, if any, scheduling restrictions, and overall hours of program operation;

(2) Admission requirements and intake procedures, including a statement that the minimum information to be collected at the intake session shall include social, economic, and family histories, educational and vocational achievement, criminal history, and medical, drug, and drug treatment histories;

(3) Fee policies and reduced fees for persons of low income. 105 CMR 750.310 shall also contain a statement indicating whether or not the program accepts public or private third party reimbursement or funding;

(4) Procedures regulating access to client records, in accord with 105 CMR 750.350, 750.360 and 750.370;

750.310: continued

(5) Program rules, including;
(a) all obligations imposed on clients and the sanctions for their violation,
(b) criteria for termination,
(c) procedures for involuntary terminations as required by 105 CMR 750.560,
(d) grievance procedure for the resolution of any other client related problem or dispute, and
(e) client rights at least to the extent guaranteed by 105 CMR 750.380.

(B) The policy manual shall be made available to all clients and/or interested parties in the following ways:
(1) Posted or hung conspicuously in an area frequented by all clients, or
(2) Kept at a central place, with a notice of its placement conspicuously posted in an area frequented by all clients; and
(3) Given to each existing client within 60 days of the effective date of 105 CMR 750.000 and to each new client during the admission process and to any interested party upon request.

(C) When furnishing a client with a copy of the policy manual or any change thereto, the licensee shall secure a dated and signed receipt which shall be placed in the client record.

(D) Whenever the licensee makes a change in policy, it shall issue a written change to the policy manual, which change shall not take effect until placed and distributed as provided for the manual itself in 105 CMR 750.310(B).

(E) The licensee may charge a reasonable fee for the cost of copying and assembling when giving a copy of the policy manual to an interested party or a second copy to a client.

750.320: Administration

(A) Each licensee shall designate a qualified administrator and shall establish by-laws or policies which describe the organization of the program, establish authority and responsibility, and identify programs and goals.

(B) The administrator or his/her designee shall at all times be on the premises of the facility while it is in operation. All staff members on duty shall know who is responsible for supervision of the program at any given time.

(C) The ownership of the facility shall be fully disclosed to the Department including the names and addressses of all owners or controlling persons whether they be individuals, partnerships, corporate bodies, or subdivisions of other bodies.

(D) The licensee shall be responsible for compliance with all applicable laws and regulations of legally authorized agencies.

(E) Each licensee shall establish a system of business management and staffing to assure that the program maintains complete and accurate accounts, books and records, including required financial, personnel, and client records.

750.330: Personnel

(A) Each licensee employing more than four persons shall describe in writing the program's current personnel policies and practices and shall make them available to all staff members. Such personnel policies shall include a description of:
(1) The criteria and procedures for recruiting, hiring, assignment, promotion, and suspension or dismissal of a staff member;
(2) The procedure for handling staff complaints;
(3) Provisions for vacations, holidays, paternity and maternity leaves, education and sick leaves, leaves of absence, and other fringe benefits;

750.330: continued

(4) Staff member accident and safety procedures;
(5) Procedures for disciplinary actions; and
(6) Procedures for work performance appraisal.

(B) The licensee shall keep and maintain an organizational chart which shall include but not be limited to, lines of authority, responsibility, communications, and when relevant staff assignment.

(C) The licensee shall make available job descriptions for all positions including salary ranges.

(D) The licensee shall provide, upon request of the Department, evidence that personnel are currently certified, licensed or registered where applicable laws require certification licensure, or registration. In addition, the licensee shall maintain accurate information on the formal and ongoing education and training of direct service staff in all diagnostic, therapy, and treatment methods which he/she utilizes or supervises.

(E) The licensee shall provide orientation for all new staff members to acquaint them with the program's philosophy, organization, program practices and goals.

(F) The licensee shall provide ongoing staff training and supervision appropriate to the size and nature of the program and staff involved.

(1) The licensee shall have available or have access to an updated drug resource library which shall contain information concerning the pharmacology, psychosocial, and legal aspects of drug use and abuse.

(2) All staff members shall be thoroughly knowledgeable about commonly abused psychotropic drugs and their physical, mental, and social implications.

(G) Where volunteers are employed in a program, they shall be well screened, trained, and supervised appropriately to aid them in fulfilling their assignments. Volunteers shall be used as an adjunct to regular paid staff and not in lieu of regular paid staff.

(H) The licensee shall evaluate all staff members in terms of job performance. Such evaluation shall be done annually and a copy placed in the employee's record.

750.340: Finances

(A) The applicant or licensee shall demonstrate financial capability to operate the program for the licensing period; programs which have not previously operated shall demonstrate such capability for at least a three month period.

(B) The licensee shall keep and maintain an accurate record of receipts and shall be audited annually, a copy of which shall be forwarded to the Department.

(C) The licensee shall keep on file an annual budget. Such budget shall categorize revenues by source of funds and expenses by service components.

(D) The licensee shall establish written procedures and policies for all fiscal operations, including policies and procedures for fee arrangements with clients.

(E) Each licensee shall have liability insurance.

750.350: Evaluation

(A) The licensee shall have an evaluation plan that will enable it to measure the progress being made in reaching its stated objectives and goals.

(B) An evaluation report shall be prepared annually by the licensee. Such report should be oriented toward the presentation of data and information that will be useful in improving program operation.

750.360: Client Records

(A) The licensee shall maintain individualized client records with an identification number that can be referenced to a distinctly separate file for client identification. The licensee shall organize its client records so that financial and administrative matters can be reviewed without disclosing clinical information.

(B) The written individual client record shall include, but not be limited to, the following information:

(1) Name, date of birth, sex, marital status, and primary language if other than English;
(2) Information listed in 105 CMR 750.310(A)(2);
(3) Referring agency or person;
(4) Sources of financial support;
(5) Presenting problem(s);
(6) Signed and dated progress notes;
(7) Original treatment plan and periodic reviews;
(8) Discharge summaries which shall include aftercare plans;
(9) Aftercare services;
(10) Follow-up attempts and services; and
(11) All necessary authorizations and consents.

(C) Progress notes shall be legible, dated, signed by the individual making the entry, and current.

(D) All client records shall be marked confidential and kept in a secure, locked location.

(E) Except as otherwise provided in 105 CMR 750.000 or by applicable state or federal law, access to client records shall be only by those staff members authorized by the administrator or his/her designee. The licensee shall have a written procedure regulating and controlling access to client records by those members of the staff whose responsibilities require such access. The licensee shall not develop any procedure prohibiting Department personnel access to client records for the purpose of review.

750.370: Confidentiality

(A) Information in a client record shall be privileged and confidential and shall only be made available:

(1) To medical personnel in a medical emergency;
(2) To qualified personnel for the purpose of conducting scientific research, management audits or program evaluations;
(3) If authorized by an order of a court of competent jurisdiction;
(4) Where authorized by the prior informed consent of the client. Such consent shall be in writing and shall contain:
  (a) the name of the program making the disclosure;
  (b) the name or title of person or organization to whom the disclosure is made;
  (c) the name of the client;
  (d) the purpose or need for the disclosure;
  (e) the extent or nature of information to be disclosed;
  (f) a statement that the consent is subject to revocation;
  (g) the date on which the consent is signed; and
  (h) the signature of the client.

(B) Any disclosure made under 105 CMR 750.370, whether with or without the client's consent, shall be limited to information necessary in light of the need or purpose for the disclosure.

(C) Authorization for release of information shall have a duration no longer than that necessary to effectuate the purpose for which it is given. Where treatment is made a condition of release from confinement, consent shall expire 60 days after it is given.

(D) Only the administrator or his/her designee shall sanction the release of information from client records.

750.370: continued

(E) A request for release of information by a client shall not be denied.

(F) All present or past staff members who have access to, knowledge of, or possess any information pertaining to, present or former clients shall be governed by 105 CMR 750.000.

(G) The licensee shall, as part of its orientation, inform all staff members and clients of these confidentiality requirements.

750.380: Client Rights

(A) The licensee shall make every effort to safeguard the legal and civil rights of each client. Each licensee shall adopt and maintain a currently updated set of program rules, which shall state the responsibilities and the rights of clients as defined by 105 CMR 750.380.

(B) Specific Client Rights.

(1) All programs, including residential programs, shall guarantee clients freedom from physical and psychological abuse and/or deprivation. At a minimum, these rights shall include freedom:

(a) from corporal punishment and/or physical abuse;
(b) from body cavity and strip searches;
(c) to have control over his/her bodily appearance;
(d) to have a hearing on any intended disciplinary measure as set forth in 105 CMR 750.560;
(e) to participate or not, in religious worship of his/her own choosing;
(f) to examine his/her client record;
(g) to challenge information in his/her client record and insert a statement of clarification;
(h) to terminate treatment at any time; and
(i) from signing over his/her public assistance, food stamps, or other income to the licensee except when it is part of a mutual treatment agreement signed by both the client and the licensee. In such case, the client has the right to know how the income is being expended.

(2) Residential programs shall guarantee clients these additional rights:

(a) to bathe, shower, and meet personal hygiene needs in a resonable manner, at a reasonable time;
(b) to have regular physical exercise;
(c) to wear his/her own clothes, unless medically contraindicated;
(d) to send and receive sealed letters. Where the licensee deems it necessary, mail shall be inspected for contraband in the presence of the client;
(e) to be given regular and private use of a pay telephone; and
(f) to have visitors at reasonable times. Visits by the client's attorney and personal physician shall not be limited.

(C) If the licensee intends any modification affecting 105 CMR 750.380(B)(2), prior to such modification a detailed written justification shall be filed With the Department and be subject to the approval of the Department. Any approved modification shall be posted conspicuously as specified in 105 CMR 750.310(B).

(D) The program rules shall also include, in addition to the disciplinary hearing procedure required by 105 CMR 750.560, a grievance procedure for the resolution of any other client related problem or dispute which arises within the program, concerning the client rights enumerated in 105 CMR 750.380(B).

750.500: Admission

(A) Each licensee shall establish written eligibility criteria for admission and shall make such criteria available to the client upon application for admission and upon request by any other person. A copy of said criteria shall be posted conspicuously in an area frequented by all clients.

(1) If an applicant does not meet eligibility requirements, the licensee shall attempt to arrange alternative placement.

(2) No person shall be denied admission solely on the basis of race, religion, color, sex, sexual preference, national origin, ancestry, or the fact that she/he has been terminated by another treatment program.

(B) The admission decision and the reason(s) for it, shall be recorded in the applicant's record.

(1) A log of applications denied admission shall be maintained by each licensee. Such log shall include:

(a) age, sex, and race of the applicant;
(b) referral source;
(c) reason for decision;
(d) date of application;
(e) date of decision.

(2) The licensee shall inform the applicant of the decision and the reason(s) for the decision.

(C) In the course of formal admission into treatment, each applicant shall be interviewed by a qualified health professional.

(1) Within 21 days of formal admission the licensee shall take a thorough personal history. Such history shall include the relevant information requested from 105 CMR 750.310(A)(2) and 750.360(B) as well as any other relevant information.

(2) Such information shall be entered in the client record.

(D) Medical and Laboratory Requirements.

(1) Residential Drug-Free Programs: As soon as possible, but no later than 21 days after admission the licensee shall provide or make arrangements for a thorough physical examination by a licensed physician. Before allowing a client to sleep in the residence, the licensee shall assure itself that the client has no infectious, communicable or contagious disease.

((2) Reserved)

(3) Methadone Treatment Programs: As soon as possible, but no later than 14 days after admission, the licensee shall conduct a thorough physical examination and laboratory tests as required by 105 CMR 750.720(A)(8), (9).

(4) Day Treatment Programs: The licensee shall elicit during the personal history interview sufficient medical information to determine whether a physical examination is necessary. If so, the licensee shall arrange for such an examination to take place.

750.510: Orientation

(A) The licensee shall assign a staff member to orient a new client to the program and the services available.

(B) The licensee shall provide a new client with an orientation session which will familiarize him/her with the rules, procedures, activities, policies, and philosophy of the program. The licensee shall specifically acquaint a new client with that part of the rules relating to the termination process and the criteria for termination.

(C) The licensee shall verbally and in writing inform the client of program requirements for client participation. The rules and procedures for disciplinary action and termination, including grievance mechanisms, shall be explained to the new client during the orientation.

750.520: Treatment Plan

(A) Upon formal admission, the licensee shall, in conjunction with the client, prepare an individual treatment plan for services.

(B) The individual treatment plan shall be developed by a team which shall include a qualified health professional and, if different, the staff member(s) responsible for implementing the plan on a daily basis.

(C) The team shall assess the educational, vocational, medical, psychiatric, psychological and other personal or social needs of the client. In formulating the treatment plan, program personnel shall negotiate in good faith with the client to assure that the treatment serves his/her individual needs.

(D) The treatment plan shall include: a statement of the short and long term treatment goals; the reasons for such goals; the type and frequency of counseling and supportive services; medication prescribed and the reasons for the prescription; dosage and plan for change thereof, if any, including planned rate of detoxification; the assignment of a primary counselor; identification of those persons responsible for coordinating and implementing the treatment plan; the probable duration of treatment; and the aftercare and follow-up services to be provided. Programs may indicate client involvement in the development of the treatment plan by making provision in the client record for a signed statement of agreement.

750.530: Periodic Review

(A) Individual treatment plans shall be reviewed with the client and amended, as necessary, no less than every 90 days for outpatient and every 30 days for day treatment and residential programs. A summary of such periodic review shall become a part of the client record.

(B) The review shall evaluate the client's progress and reassess his/her needs.

(C) The review shall be conducted by a team similarly constituted as that described in 105 CMR 750.520(B).

750.540: Treatment Services

(A) The licensee shall provide or make arrangements for the provision of counseling services as part of total treatment. The sessions shall be conducted by trained personnel under the supervision of a qualified health professional.

(B) The licensee shall have available to staff on a regular basis, medical and psychiatric consultation.

(C) The licensee shall provide or make arrangements for the provision of appropriate care for those clients who evidence medical or psychiatric problems.

(D) The licensee shall have written agreements with appropriate community agencies and individuals which assure the availability of qualified medical and mental health care.

(1) Inpatient and residential programs shall have emergency care available on a 24 hour, seven day per week basis.

(2) The licensee shall make provisions for isolating clients where illness requires such isolation.

(3) Outpatient and methadone treatment programs shall assure the availability of appropriate inpatient care for emergency purposes.

(4) All other programs shall have emergency care accessible at least during their hours of operation.

750.550: Community Relationships

(A) The licensee shall maintain written formal agreements with appropriate community agencies in order that clients may have available to them a wide range of services. Such formal relationships shall include, but not be limited to, medical, dental, mental health, vocational, and educational agencies.

(B) The licensee shall maintain an up-to-date resource and reference file of all agencies of potential usefulness to clients. The resource and referral file shall contain sufficient detail to allow staff members making referrals to determine:

(1) The name, location, contact person, and telephone number of the resource;
(2) The types of service the resource is able to provide;
(3) The resource's eligibility criteria; and
(4) The type of follow-up information that the resource will provide.

750.560: Termination

Each licensee shall establish and maintain written procedures detailing the termination process and shall incorporate them into the policy manual as described in 105 CMR 750.310. These procedures shall include:

(A) Written criteria for termination, defining:

(1) Successful completion of program;
(2) Voluntary termination prior to program completion;
(3) Involuntary termination;
(4) Medical Discharge; and
(5) Transfers and referrals.

(B) Rules of required conduct and procedures for both emergency and non-emergency involuntary terminations in accordance with the following requirements:

(1) In an emergency situation, the licensee may suspend a client immediately and without provision for detoxification where the client's continuance in the program presents an immediate and substantial threat of physical harm to other clients or program personnel or property; or where the continued treatment of a client presents a serious medical risk as determined by the program's medical director, but the client shall be afforded a review thereafter, including the opportunity to be heard no later than seven days from the client's receipt of the written notice of suspension, all as provided in 105 CMR 750.560(B)(2).

(2) In a non-emergency situation, wherein the client's continuance does not present the immediate and substantial threat or serious medical risk described in 105 CMR 750.560(B)(1), the licensee may not terminate, suspend or commence any involuntary detoxification on the client without first affording him/her the following procedural rights:

(a) prompt written notice which shall contain:

1. a statement of the reasons for the proposed termination, (*e.g.* violations of a specific rule or rules, non-compliance with treatment contract, *etc.*) and the particulars of the infraction including the date, time and place;
2. notification that the client has the right to request a hearing within the time specified by the licensee to appeal the proposed termination;
3. the date, time and place of the hearing, if the client elects to be heard; and
4. a copy of the licensee's hearing procedure.

(b) an opportunity to be heard at a hearing conducted in accordance with the procedures specified hereafter:

1. The hearing shall be presided over by an impartial hearing officer or officers who may be any staff or other person not directly involved in either the facts of the incident giving rise to the disciplinary proceeding or in the decision to commence the proceeding; provided that the persons involved in either the facts of the incident or in the decision to commence the proceeding shall not have authority over the hearing officer(s);
2. The client may be represented at the hearing by any responsible adult of the client's own choosing, including counsel;

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3. The hearing shall be conducted in accordance with previously established written rules which need not be the rules of evidence used in judicial proceedings, but which shall be designed to ensure a fair and impartial proceeding, provided that the program shall clearly establish that the client did commit the alleged violation;

4. The client shall be entitled, upon request, to examine any documentary evidence in the possession of the licensee which pertains to the subject matter of the hearing;

5. The client shall be entitled to call his/her own witness and to question any adverse witness;

6. The client and/or licensee may record the hearing by any means of his/her own choosing and at his/her own expense, provided that the means of recording does not substantially interfere with the proceedings.

(c) The hearing officer will make his/her decision within seven days after the hearing and will base the decision solely upon the information presented at the hearing. The decision shall also be based upon clinic rules and regulations that were in effect at the time of the violation and had previously been posted.

(d) The hearing officer shall provide the client with his/her decision in writing which shall include an explanation of the reasons for the decision and will provide the client (and his/her representative, if requested) with a copy thereof.

(e) If the licensee affords the client an appeal from an adverse decision of the hearing officer, the licensee may not terminate, suspend or impose any lesser sanction on the client without first receiving and insuring that the client also receives, the decision on appeal.

(f) Clients in a methadone treatment program or residential detoxification program, if terminated or suspended in accordance with 105 CMR 750.560(B)(2), shall, and if terminated or suspended in accord with 105 CMR 750.560(B)(1), may, at the licensee's discretion, be afforded the opportunity of detoxification. The rate of detoxification shall be determined by the program's Medical Director to be appropriate to the dosage level at which the client was being medicated before the final decision was made to terminate or suspend; and the licensee shall either itself detoxify the client or make arrangements for appropriate detoxification in another facility.

(C) Upon every termination the program shall prepare and include in the client record a written summary containing, but not limited to, the following information:

(1) Description of treatment episode;
(2) Current drug usage;
(3) Maintenance level at time of discharge;
(4) Vocational/educational achievements;
(5) Criminal activity;
(6) Reason for termination;
(7) A summary of any disciplinary action taken, including:
  (a) the reasons therefor;
  (b) either the termination plan or the decision of the grievance hearing, or, if the client did not elect to be heard, a clear statement of the circumstances of termination, suspension or any lesser sanction imposed;
  (c) the location of the client immediately after discharge; and
(8) Referrals.

(D) In the case of a medical discharge, the licensee, before such termination, shall develop together with the client a written termination plan.

(1) The termination planning shall be conducted by a team similarly constituted as that which developed the treatment plan;
(2) The team shall assess the client's needs and develop a termination plan to meet these needs, including provision for aftercare and follow-up services where appropriate;
(3) The termination plan shall be signed by both the client and the primary counselor.

(E) A copy of the summary (and termination plan where appropriate) shall be placed in the client record.

750.570: Follow-Up

(A) The licensee shall, when possible and appropriate and with the consent of the client, maintain contact with each client for at least one year after discharge.

(B) Follow-up efforts shall be documented in the client record.

750.700: Residential Treatment Programs

(A) Residential Drug-Free Programs.

(1) Residential drug-free programs shall provide 24 hour staff and telephone coverage, seven days per week. Senior residents in treatment shall not be considered staff for this purpose.

(2) Programs shall have adequate and identifiable staff responsible for administrative, clinical and support services. Staffing shall be sufficient to provide required services for the stated bed capacity.

(3) As soon as possible, but not later than 21 days after admission, the licensee shall provide or make arrangements for the provision of a thorough physical examination by a licensed physician.

(a) Where physical and laboratory examination so indicate, the licensee shall provide or make referral arrangements for the provision of appropriate medical and/or other care.

(b) Before allowing a client to sleep in the residence, the licensee shall assure itself that the client has no infectious, communicable disease.

(4) The licensee shall provide counseling, no less than five times per week.

(a) At a minimum, one of the five sessions must be an individual counseling session;

(b) Types of counseling sessions shall be as specified in the individual treatment plan;

(c) Counseling services shall also include:

1. group treatment;
2. family and/or couples counseling; and
3. vocational guidance.

(5) The licensee shall also provide or make referral arrangements for the provision of the following services:

(a) advocacy/ombudsman services;
(b) job placement assistance;
(c) recreational services;
(d) substance abuse education and information;
(e) general education; and
(f) legal aid.

(6) The licensee shall provide or make referral arrangements for the provision of psychiatric, medical, social, and dental services as needed.

(7) Where the licensee utilizes an outside agency(ies) for the provision of services, formal written agreements shall be maintained and re-affirmed at least bi-annually.

(8) All new employees shall receive a chest x-ray or an intradermal skin test for tuberculosis.

(9) Aftercare:

(a) The licensee shall provide or make referral arrangements for the provision of counseling and other supportive services.

(b) The licensee shall maintain and make available to clients as needed a file of available community services which shall include a description of the services, its address and phone number, and the name of a person to contact.

(c) The licensee shall prepare the client for appropriate referral, as necessary.

(d) Aftercare services shall be documented in the client record.

750.710: Ambulatory Treatment Programs

(A) Day Treatment Programs.

(1) A Day Treatment program shall operate a minimum of five hours per day, five days per week.

750.710: continued

(2) The licensee shall obtain from each client sufficient medical information such that it can be determined whether a physical examination is necessary. If so indicated, the licensee shall arrange for such an examination to be provided. Where a physical and/or laboratory examination indicates, the licensee shall provide or make referral arrangements for the provision of appropriate medical and/or other care.

(3) The licensee shall provide counseling no less than five times per week.

(a) At a minimum, one of the five sessions must be an individual counseling session.

(b) Types of counseling sessions shall be as specified in the individual treatment plan.

(c) Other counseling services that may be offered include:

1. group;
2. family and/or couples; and
3. vocational guidance.

(4) The licensee shall also provide or make referral arrangements for the provision of the following:

(a) referral;
(b) vocational counseling;
(c) job placement assistance;
(d) substance abuse education and information;
(e) general education; and
(f) legal aid.

(5) The licensee shall provide or make referral arrangements for the provision of psychiatric, medical, social, and dental services as needed.

(6) Where the licensee utilizes an outside agency(ies) for the provision of services, formal written agreements shall be maintained and re-affirmed at least bi-annually.

(B) Crisis Intervention Program.

(1) A Crisis Intervention program shall provide the following:

(a) Immediate crisis intervention counseling as needed;

(b) In crisis situations the licensee shall obtain at a minimum the following information:

1. drugs used within the last 48 hours;
2. drugs used in combination; and
3. dosages used.

(c) The licensee shall make a determination as soon as possible after the crisis situation is over whether referral for more extensive treatment is required and, if so, to make arrangements for such treatment.

(d) The licensee, in addition to providing crisis intervention services, shall be able to provide information about drugs, identification of drugs, and information about drug treatment, drug treatment facilities and emergency treatment centers.

(e) The licensee shall have written procedures:

1. concerning the limitations of emergency treatment to be carried out by the program staff members;
2. for dealing with anticipated medical and psychiatric emergencies; and
3. for handling problems such as unconscious individuals, minors, individuals with communicable diseases, and individuals requiring transfer to a hospital.

(f) The licensee shall have formal written agreements with appropriate community agencies, hospitals, mental health centers and individuals which assure the availability of qualified medical and mental health care. Such agreements shall be re-affirmed annually.

(g) The licensee shall maintain an up-to-date resource and referral file of all available emergency services and other appropriate community agencies of potential usefulness to clients. This file shall include:

1. emergency medical services;
2. emergency rescue care;
3. emergency transportation;
4. available detoxification services;
5. available legal services;
6. available methadone maintenance centers;

750.710: continued

7. mental health care;
8. public health services (V.D. clinics, pregnancy tests, *etc.*), physical and psychiatric services, such as public hospitals, child guidance centers, family consultation services, mental health clinics, etc.;
9. emergency short-term housing and food services;
10. poison control centers; and
11. police and fire departments.

(2) Community Relations and Referrals. The licensee shall maintain ongoing relationships with community agencies in order that clients may have available to them a wide range of services.

(3) Referral Verification. The licensee shall contact the agency to which a referral has been made to determine the status of the referral. Such contact shall be done in a manner that does not violate the confidentiality of the referral.

750.720: Methadone Treatment Programs

(A) General Requirements.

(1) Methadone treatment programs, in addition to providing medication and evaluation, shall provide, at a minimum, counseling, rehabilitation and other social services including vocational, educational and employment guidance, which will help the client become a well functioning member of society. These services may be made available at the primary facility, but the licensee is permitted to enter into formal, written agreements with private or public agencies, organizations, or institutions for these services. Such agreements shall be maintained and re-affirmed at least bi-annually. Evidence will be required to demonstrate that the services are fully available and are being utilized.

(2) The licensee shall operate in accordance with:
(a) M.G.L. c. 94C;
(b) the rules and regulations of the Federal Food and Drug Administration (FDA);
(c) the rules and regulations of the Drug Enforcement Administration (DEA); and
(d) the State Methadone Authority.

(3) The licensee shall designate a licensed practitioner as medical director. The medical director shall be responsible for administering all medical services performed by the program, be licensed to practice medicine in the Commonwealth of Massachusetts, and where possible have experience in working with drug dependant persons. In addition, the medical director, or any other authorized staff physician shall be responsible for the following minimal requirements:
(a) ensuring that evidence of current physiological dependence is recorded in the client record;
(b) ensuring that a medical evaluation, including a medical history has been taken;
(c) ensuring that appropriate laboratory studies have been performed;
(d) signing or countersigning all medical orders; and
(e) reviewing and countersigning treatment plans at least annually.

(4) The licensee shall maintain security over stocks of all chemotherapeutic substances, and over the manner in which they are received, stored and distributed, according to the guidelines established by the DEA.

(5) The licensee shall have an adequate system for identifying clients when dispensing chemotherapeutic substances.

(6) Methadone treatment programs shall provide services seven days per week if delivering detoxification services and a minimum of six days per week if delivering only maintenance services. Consideration should be given to the employment, homemaking and educational needs of the clients. Services provided on at least five of these six or seven days shall be on the basis of an eight-hour day provided that a minimum of two hours of such eight-hour must be scheduled at a time other than the regular 9:00 A.M. to 5:00 P.M. day. Services administered during the remaining one or two days must be scheduled for a period of at least four hours.

(7) Prior to admitting a client into treatment, the licensee shall obtain and shall make a part of the client record:

750.720: continued

(a) Form FD-2635, "Consent to Methadone Treatment" as required by the FDA, signed by the client. The licensee shall insure that the client signs with full knowledge and understanding of its contents. Where the client is under the age of 18, the consent form shall be signed by the client and the client's parent or guardian.

(b) A statement, developed by the program which, at a minimum, addresses:

1. distinction between detoxification and maintenance;
2. approximate length of stay in treatment for each modality;
3. a clear statement of the goals of each type of treatment;
4. the options available to both the client and the program as a result of either a voluntary or involuntary termination, as stated in 105 CMR 750.560; and
5. a client signed receipt for the statement shall be placed in the client record.

(c) Two or more proofs of narcotic dependence; such proofs may consist of:

1. two or more positive urine tests for opiate or morphine-like drugs;
2. the presence of old and fresh needle marks;
3. early physical signs of withdrawal;
4. documented evidence from the medical and personal history;
5. physical examination; and
6. laboratory tests.

(8) Physical Examination. Each client shall have a physical examination by a program physician or a qualified health-care professional under the supervision of a program physician as soon as possible, but no later than 14 days after admission.

(a) The physical examination shall consist of an investigation of the organ systems for possibilities of infectious disease, pulmonary, liver and cardiac abnormalities, and dermatologic sequelae of addiction. In addition, the physical examination shall include a determination of the client's vital signs (temperature, pulse, blood pressure and respiratory rate); an examination of the general appearance; head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs and breasts), abdomen, extremities, skin and neurological assessment; and the physician's overall impression of the client.

(b) Prior to prescribing, dispensing or administering methadone, the licensee shall assure itself that the methadone will not interfere with any other drugs the client is taking.

(9) Laboratory Tests. A laboratory work-up shall be performed by qualified personnel as soon as possible, but no later than 14 days after admission. When a client is readmitted to a program, it is recommended that the decision determining the appropriate laboratory tests to be conducted be based on the intervening medical history and a physical examination.

(a) the laboratory work-up shall include:

1. serological test for syphilis;
2. tuberculin skin test; and
3. urine screening for drug determination.

(b) The licensee shall ensure that an initial drug screening urinalysis for opiates, barbiturates, amphetamines, cocaine, and other drugs as appropriate is completed for each prospective client and that when urine is collected, specimens from each client are collected in a manner that minimizes falsification.

(c) Laboratories used for urine testing shall be approved by the FDA and the State Methadone Authority.

(d) It is recommended practice that the following laboratory examinations be conducted for each client upon admission to a program in addition to the required examinations stated above:

1. complete blood count and differential;
2. routine and microscopic urinalysis;
3. liver function profile, *e.g.* SGOT, SGBT, *etc.*;
4. when the tuberculin skin test is positive, a chest x-ray;
5. Australian Antigen HB Ag Testing (HAA testing);
6. when clinically indicated, an EKG; and
7. where appropriate, a pregnancy test and a pap smear.

(e) Laboratories shall be approved by the Department.

(10) Counseling Services. Methadone Treatment programs shall offer counseling services in accordance with 105 CMR 750.710(A)(3) and (4).

750.720: continued

(11) The licensee shall begin treatment by giving small dosages individually adjusted to the narcotic tolerance of the new client.

(12) The licensee shall report within 14 days of occurrence to the FDA on Form-1639 a detailed account of any adverse physical or psychological reactions.

(B) Methadone Detoxification.

(1) A Methadone Detoxification program shall detemine separately for each client, in accordance with 105 CMR 750.520, the rate at which methadone is to be decreased. Clients who are being detoxified as a planned goal in a methadone maintenance program may enter into an agreement with the progam for a blind detoxification. Such agreement shall be renewed only by mutual consent on a regular basis. The maximum period between an agreement and a renewal shall be 60 days.

(2) A waiting period of at least one week shall be required between detoxification attempts. Before a detoxification attempt is repeated, the medical director, or any other authorized staff physician, shall document in the client record that the client continues to be or is again physiologically dependent on a narcotic drug.

(3) All requirements for maintenance treatment apply to detoxification treatment with the following exceptions:

(a) A history of one year physiologic dependence is not required for admission;

(b) Clients who have been determined by the program physician to be currently physiologically narcotic dependent may be detoxified with methadone, regardless of age;

(c) No urine testing is required except for the initial drug screening urinalysis;

(d) Periodic treatment plan evaluations required for maintenance clients are not necessary; and

(e) The requirements of 21 CFR 291.505(d)(6): *Federal Treatment Standards* [except (d)(6)(ii)(a) through (d)(iii) and (iv)]", do not apply to detoxification treatment.

(4) The licensee shall dispense methadone daily at the facility under the direct supervision of a physician or other qualified medical person.

(5) The licensee shall not provide take home medication.

(C) Methadone Maintenance.

(1) All clients receiving methadone maintenance shall be given careful consideration for discontinuation of methadone use. Social rehabilitation shall have been maintained for a reasonable period of time. Clients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free whenever possible, although it is recognized that for some clients the drug may be needed for a longer period of time. In those instances where a client is being maintained for a period in excess of two years, the licensee shall document in the client record the justification for continued maintenance and the therapeutic use of take-home medication or the contraindication thereof.

(2) No applicant shall be admitted unless she/he has at least a documented history of opiate dependency beginning one year prior to application for treatment. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting physician may, in his/her reasonable clinical judgment, admit the person to methadone maintenance treatment, if from the evidence presented, observed, and recorded in the client record, it is reasonable to conclude that there was physiologic dependence at a time approximately one year prior to admission.

(3) Urine Testing.

(a) An initial drug-screening shall be completed for each prospective client;

(b) At least eight additional random urinalysis shall be performed on each client during the first year in treatment;

(c) At least quarterly random urinalysis shall be performed on each client in treatment for more than one year; and

(d) Results of urine testing shall be used as one clinical tool for the purposes of diagnosis, and in determination of treatment plans, as well as by monitoring client drug-use patterns before and during treatment. The licensee shall ensure that urine test results are not used to force a client out of treatment but are used as an aid in making treatment decisions.

750.720: continued

(4) Administration of Methadone.

(a) After at least three months of maintenance treatment and after showing substantial progress in rehabilitation by participating actively in the program activities and/or participation in educational, vocational, homemaking activities, those clients whose employment, education or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times per week the times when they must ingest the methadone under observation. The licensee shall dispense no more than a two day take home supply to the client. The licensee shall observe utmost care in authorizing take home privileges and the reasons for such shall be documented in the client record.

(b) After at least two years of maintenance treatment and where rehabilitative progress would be enhanced by decreasing the frequency of client attendance, the client may be permitted to reduce to twice weekly the times she/he must ingest the methadone under observation. The licensee shall dispense no more than a three day take home supply.

(c) The requirements for when the methadone must be ingested under observation may be relaxed if the client has a serious physical disability. The FDA and the Department shall be notified of such cases. The reasons for take home privileges shall be documented in the client record.

(d) In exceptional circumstances, the licensee may dispense additional methadone for a specific period where client hardship would result from requiring the customary methadone intake. The licensee shall record the reasons for providing additional methadone in the client record.

(e) In circumstances of severe illness, infirmity or physical disability, an authorized individual may deliver or obtain the methadone. The reasons for this exception shall be entered in the client record.

(f) Take home privileges may be revoked or suspended if the client does not maintain those behavior changes which allowed take out privileges in the first place.

(5) Pregnant Women.

(a) Pregnant clients, regardless of age, who have had a documented narcotic dependency in the past and who may be in direct jeopardy of returning to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such clients, evidence of current physiological dependence on narcotic drugs is not needed if the medical director, or any other authorized staff physician, certifies the pregnancy and, in his/her reasonable clinical judgment, finds such treatment to be medically justified. Evidence of all findings shall be recorded in the client record.

(b) The licensee shall take caution in the maintenance of pregnant women. Dosage levels shall be maintained as low as possible if continued methadone maintenance is deemed necessary. It is the responsibility of the licensee to ensure that each pregnant client is fully informed concerning the possible risks to herself and to her unborn child.

(c) The licensee shall make referral arrangements for the provision of pre-natal and delivery services.

(6) Termination.

(a) Upon successfully reaching a drug-free state, the client should be maintained in the program as long as necessary to assure stability.

(b) Clients suspended or involuntarily terminated shall be afforded the opportunity of detoxification in accordance with 105 CMR 750.560. Upon the request of the client or where appropriate, the licensee shall make arrangements for an immediate transfer to another facility, if possible. Where transfer is not possible, other arrangements for detoxification shall be made.

750.800: General Requirements

(A) Facilities shall comply with all state laws and local ordinances applicable to buildings, fire protection, public safety and public health.

(1) The licensee shall have a certification of inspection from the Department of Public Safety or the appropriate local building inspector.

(2) The licensee shall obtain for the facility certification by the local Board of Health or Health Department and shall keep written reports of inspection on file in the facility.

(3) The licensee shall request from the local fire department semi-annual fire inspections in each facility. Such inspections shall be recorded and put on file by the licensee.

(B) The licensee shall establish a written plan detailing procedures for meeting potential emergencies:

(1) The plan shall include:

(a) procedures for the assignment of personnel to specific tasks and responsibilities in emergency situations;

(b) instructions relating to the use of alarm systems and signals;

(c) systems for notification of appropriate persons; and

(d) specification of evacuation routes and procedures.

(2) The licensee shall post the plans and procedures at suitable locations throughout the facility. Staff and clients shall familiarize themselves with them.

(C) The licensee shall, where appropriate, conduct emergency drills at least quarterly.

((1) Reserved)

(2) Long term residential programs shall assure themselves of client capability for self-preservation and conduct fire drills under varied conditions in order to:

(a) insure that clients and staff are familiar with evacuation routes and procedures;

(b) insure that clients and staff can evacuate the facility in an orderly and safe manner;

(c) insure that all staff members and clients are trained to perform assigned tasks;

(d) insure that designated staff members are familiar with the use of the fire-fighting equipment in the facility; and

(e) evaluate the effectiveness of emergency plans and procedures.

(3) In residential facilities, fire drills shall be conducted on all shifts.

(D) The design, construction, and furnishings of the facility shall be appropriate for fostering personal and social development, and be flexible enough to accommodate the needs of the clients and the treatment philosophy of the program.

(E) All doorways and corridors and stairwells shall be maintained so as to provide free and unobstructed egress from all parts of the facility:

(1) An emergency source of lighting shall be available in all corridors and stairways that lead to the principal means of egress;

(2) All stairways shall be equipped with handrails; and

(3) The licensee shall eliminate barriers that would restrict the movement of handicapped persons.

(F) All facilities shall provide sufficient housekeeping and maintenance personnel to maintain the interior of the facility in good repair and in safe, clean, orderly, attractive, and sanitary manner free from all accumulation of dirt, rubbish, and objectionable odor.

(1) Floors, walls, and ceilings shall be cleaned regularly; walls and ceilings shall be maintained free from cracks and falling plaster.

(2) All windows, including combination windows, shall be washed inside and outside at least twice a year.

(3) Windows and doors shall be properly screened during the insect breeding season.

(4) Storage areas, attics, and cellars shall be kept safe and free from accumulations of extraneous materials such as refuse, furniture, and old newspapers or other paper goods. Combustibles such as cleaning rags and compounds shall be kept in closed metal containers.

(5) The grounds shall be kept free of refuse and litter, and areas around buildings, sidewalks, gardens and patios kept clear of dense undergrowth and ice.

750.800: continued

(G) Plumbing and heating utilities shall be adequate to maintain a healthy environment for the clients.

(1) Hot water supplied to fixtures accessible to clients shall be controlled to provide a maximum temperature of 110°F.

(2) The heating system shall be in conformity with the rules and regulations as outlined by the Department of Public Safety under M.G.L. c. 148, as amended.

(3) Every facility shall be equipped with a heating system that is sufficient to maintain a minimum temperature of 68°F throughout the facility at all times at winter temperatures. Portable heaters, such as space heaters, electric heaters or heaters using kerosene, gas, or other open-flame method are prohibited.

(4) Adequate electric lighting maintained in good repair shall be provided throughout the facility in accordance with the provisions of the M.G.L. c. 111, § 72C as amended and the recommended levels of the Illumination Engineering Society. All electrical installations shall be in accordance with the Department of Public Safety (520 CMR), Board of Fire Prevention Regulations (527 CMR), Massachusetts Electrical Code (527 CMR), and all local regulations.

750.810: Health

(A) The licensee shall keep first aid supplies in a convenient and safe place ready to be used for minor injuries.

(B) Bathrooms shall be conveniently located throughout the facility.

(1) Every bathroom door lock shall be designed so that in an emergency the locked door can be opened from the outside.

(2) Bathrooms shall be designed to ensure privacy. All toilets shall have seats.

(3) Bathrooms shall either have natural or mechanical ventilation devices.

(4) Bathrooms shall be cleaned frequently and be maintained in a sanitary manner and in good repair.

(5) A soap dispenser, paper or individual towels, toilet tissue and a mirror shall be available at all times.

750.820: Residential Facilities

(A) Each facility defined as a "group residence" under Section 424.1 of the State Building Code shall meet the building code applicable to "group residence" (*See* 780 CMR).

(B) Each facility not defined as a "group residence" under Public Safety Law or by regulations of the Building Code Commission shall meet the building codes applicable to the facility.

(C) All health and sanitation standards set-forth in 105 CMR 750.000 shall comply with 105 CMR 410.000: *State Sanitary Code Chapter II: Minimum Standards of Fitness for Human Habitation.* If a discrepancy exists between 105 CMR 750.000 and 105 CMR 410.000, the more stringent shall take precedence.

(D) Environment.

(1) The exterior of the residence shall, wherever possible, conform with other houses in the area. Evidence to the general public that the house is being maintained as a residential facility shall, whenever possible, not be apparent.

(2) The licensee shall design and furnish its residential facility to provide a homelike setting:

(a) There shall be proper separation in sleeping quarters and bathroom facilities serving male and female residents;

(b) There shall be one or more living rooms or day rooms. The living room area shall not be used as a bedroom for any resident or resident staff;

(c) There shall be space available for meetings, T.V. viewing, and a quiet area. These areas shall not be used as bedrooms for any resident or resident staff;

750.820: continued

(d) There shall be room for office space for staff, house records, and telephone. If records are kept in the office they shall be under lock and key, and so placed that only the house staff have access to them;

(e) There shall be a separate area set aside for individual counseling; and

(f) The master key to all rooms which may be locked by residents on the inside shall be kept where it is available to the manager and assistants in an emergency.

(E) Sleeping Areas.

(1) All sleeping areas shall be conveniently located near toilet, lavatory, and bathing facilities.

(2) Sleeping areas shall be designed to promote comfort and shall provide adequate space and privacy for residents and shall:

(a) Be large enough for the placement of needed furniture and to allow for easy passage between beds and other items of furniture. Sleeping areas shall have a minimum of 50 square feet of floor area per resident;

(b) Have adequate lighting and ventilation so that residents are comfortable in all seasons of the year;

(c) Have direct outside exposure with adequate, unobstructed natural light and adequate ventilation; and

(d) areas in accordance with the minimum temperatures set forth in 105 CMR 410.000.

(3) Residential care shall accommodate no more than six residents per sleeping area. Exceptions may be allowed for facilities upon written approval of the Department.

(4) No unfinished attic, stairway, hall, or room commonly used for other purposes shall be used as a sleeping room for any resident.

(5) Each resident shall be provided with the following basic equipment and supplies:

(a) A comfortable bed of household size. Cots and folding beds are prohibited unless used for emergency purposes;

(b) Bed springs and a clean, comfortable mattress with waterproof covering on all beds. Each mattress shall be at least four inches thick, 36 inches wide, and not less than 72 inches long;

(c) An adequate supply of clean, ironed or drip dry bed linen, blankets, bedspreads, washcloths, and towels of good quality and in good condition. This shall mean a supply of linen equal to at least three times the usual occupancy. Linen, towels, and washcloths shall be changed and laundered at least every week; and

(d) A bedside cabinet, or table dresser, drawer space, and adequate closet space.

(6) Residents should be allowed to decorate their sleeping areas with their personal possessions, such as pictures and posters.

(F) Dietary Services.

(1) Persons working in the food service area shall be free of infections, communicable diseases, and open skin lesions. The facility's health policies for persons working in the food service area shall be in compliance with state and local health laws and regulations.

(2) The licensee shall have written procedures for protecting food from contamination and spoilage during its storage, preparation, distribution, and service. Procedures shall be established for:

(a) procuring all food from sources that provide assurance that the food is processed under regulated quality and sanitation controls;

(b) clearly labeling supplies;

(c) storing all non-food supplies in an area separate from that in which food supplies are stored;

(d) storing perishable foods at proper temperatures;

(e) ensuring that any walk-in refrigerators or freezers can be opened from the inside even if locked;

(f) providing adequate hand-washing and drying facilities in convenient places;

(g) thorough cleansing and sanitizing of all working surfaces, utensils, and equipment after each period of use; and

(h) maintaining frozen foods at temperatures below 10°F.

750.820: continued

(3) The licensee shall provide sanitary storage space in cabinets for the proper storage of dishes, silverware, and cooking equipment which shall be maintained in a sanitary manner and in good repair.

(4) Dishes shall be washed and rinsed in a manner that is consistent with local health requirements.

(5) The licensee shall provide for the sanitary disposal of garbage and solid waste.

(6) The licensee shall provide dining areas which are clean, well lighted, ventilated, and attractively furnished. The dining room shall be large enough to accomodate all residents, but not necessarily simultaneously. Any area which is designated as the dining area shall not be used as a bedroom by any resident or resident staff.

(7) The licensee shall provide a nourishing well-balanced diet to all residents.

(G) Personal Hygiene.

(1) Adequate toilets, handwashing sinks, baths and showers shall be provided on floors where residents' rooms are located.

(2) Toilet, handwashing and bathing equipment and areas must be kept in good repair, and the floor area surrounding the toilet must be maintained in a sanitary manner and in good repair:

(a) A shower or tub shall be provided in a ratio of at least one per ten residents. Separate showers or tub baths for males and females are required, only if they are located in the same room with toilets. (Exceptions may be made upon written approval of the Department).

(b) Bathing tubs, showers, and sinks shall be cleaned after each use and tub and shower surfaces shall be provided with abrasive material to provide safe footing.

(H) The licensee shall provide or make available accommodations for the laundering and ironing of residents' clothing.

(I) Residents' special belongings shall be kept in a manner that will protect them from loss, theft, or misuse by others. Except when therapeutically contraindicated, residents should have ready access to their belongings.

REGULATORY AUTHORITY

105 CMR 750.000: St. 1981, c. 704; c. 111E, § 7.

(105 CMR 751.000 through 799.000: RESERVED)

(PAGES 4201 THROUGH 4250 ARE RESERVED FOR FUTURE USE.)

105 CMR 800.000: REQUIRED REQUESTS FOR ANATOMICAL DONATIONS

Section

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800.001: Purpose

(A) 105 CMR 800.000 sets forth for the purpose of interpreting and implementing M.G.L. c. 113, §§ 8 through 14.

(B) It is the intent of the law and the regulations to establish a uniform system of requesting consent to anatomical gifts in order to increase the supply of organs and tissues for the purposes of transplantation, therapy, research and education.

800.002: Citation

105 CMR 800.000 shall be cited as 105 CMR 800.000: *Required Requests for Anatomical Donations.*

800.003: Scope

105 CMR 800.000 shall govern Requests for Consent to Anatomical Donations pursuant to M.G.L. c. 113. Any section of 105 CMR 800.000 may be severed or altered without affecting the enforceability of the remaining sections.

800.004: Definitions

As used in 105 CMR 800.004 the following terms shall have the following meanings unless the context or subject matter clearly requires a different interpretation.

Acute Hospital means any hospital licensed under M.G.L. c. 111, § 51, and the teaching hospital of the University of Massachusetts medical school, (which contain a majority of medical-surgical, pediatric, obstetric, and maternity beds), as defined by the Department of Public Health.

Brain Death means total and irreversible cessation of spontaneous brain functions and further attempts are resuscitation or continued supportive maintenance would not be successful in restoring such functions. *Commonwealth v. Golston, 373 Mass 249, 366 N.E. 2d 744, (1977).*

Commissioner means the Commissioner of the Department of Public Health.

Consent means informed decision to grant permission for organ donation, living or post humous. Evidence of donative intent must be placed in and made part of the donor's medical record by either of the following forms of documentation:

(1) Donor card signed by or for donor in the presence of two competent witnesses;

800.004: continued

(2) Hospital consent form signed by person(s) of highest priority class available who is qualified to give consent and the designated representative. *See* 105 CMR 800.030(B).

(3) (a) Recorded telephone conversation or other form of recorded telecommunication of person of highest priority qualified to give consent, reduced to writing and attested to by one witness, and the designated representative; or

(b) Telegraphic message of such person identifying the sender and relationship to potential donor.

(4) Will - document bearing signature of decedent, completed in the presence of two competent witnesses, setting forth disposition of body or part thereof upon death.

(5) Document other than a will such as, but not limited to, donor card signed by donor setting out specific donation.

Death or Time of Death means determination of point in time at which death occurred as certified by a physician who attends the donor, or if none; legal certification of death by a physician in keeping with currently acceptable medical criteria.

Decedent means a deceased individual and includes a stillborn infant or fetus.

Department means the Department of Public Health.

Designated Representative means a person(s) appointed by the hospital administrator/director to inform any person qualified to give consent of the opportunity to make an anatomical gift.

Donee means any person or legal entity qualified under state laws to become recipients of bodies or part thereof as listed in M.G.L. c. 113, § 9 (hospitals, physicians/surgeons, accredited medical and dental schools, colleges or universities for education and research, bank or storage facilities).

Donor means a person who has authorized or a decedent whose organ(s) or tissue(s) has been authorized for removal pursuant to the formalities of consent as stated in 105 CMR 800.030.

Hospital means a hospital licensed, accredited or approved under the laws of any state and includes a hospital operated by the United States government, a state or a subdivision thereof, although not required to be licensed under state laws.

Initial Medical Criteria means the standards for screening potential donors established by the New England Organ Bank. A copy of these criteria shall be available from the Department.

Living Donor means a person who by a document other than a will makes a gift of his/her body part for the purpose of transplantation at such time prior to death as specified in said document.

Minimal Preservation Procedure means technique, including administration of preservation fluid, by which the organ(s) and/or tissue(s) of a potential donor is preserved for future transplantation. *See* 105 CMR 800.037.

Order of Priority means ranking of person(s) qualified for the purpose of consent who is authorized or under obligation to dispose of the body of the decedent.

Organ or Tissue Bank or Storage Facility means a hospital, laboratory or other facility licensed or approved by the Department for storage of human bodies or parts thereof, for use in medical education, research, therapy or transplantation to individuals.

Part means organs, tissues, (skin, eyes, bones, arteries, blood or other body fluids) and other portions of a human body; and "part" includes "parts".

Person means an individual, corporation, government or governmental subdivision or agency, business trust, estate trust, partnership, association, or any other legal entity.

800.001: continued

Physician or Surgeon mean a physician or surgeon licensed or authorized to practice under the laws of any state.

Pre-mortem Tests means any examinations, tests, or procedures performed after consent is given prior to death that are determined necessary to assure medical acceptability of the gift for purpose(s) intended by the donor.

Potential Donor means a person who meets the initial medical criteria for screening.

Record of Donations means book kept by hospital for the purpose of recording anatomical gifts as required by M.G.L. c. 113, § 8(c).

State means any state, commonwealth, district, territory, insular possession, and any other area subject to the legislative authority of the United States of America.

Undue Emotional Stress means a state of excitation or extreme sensitivity observed in the next of kin when information about a donation is sought even under circumstances where precautions have been exercised as indicated in Conditions Under Which Requests For Donations are not Required. *See* 105 CMR 800.036.

800.030: Consent Procedures

(A) Consent Requirements for Qualified Persons. Any consent to an anatomical gift by a person as authorized in this section shall be given by a document bearing the signature of said person. Recorded telephonic or other recorded telecommunication message shall be reduced to writing and entered into the decedent's medical record. One person in addition to the designated representative shall witness and sign. Telegraphic communication shall be made a part of the donor's medical record.

Consent or refusal need only be obtained from any person in the highest priority class available, in person or by telephone, when persons in prior classes have been sought and are not available at the time of death.

(1) Documentation of a Telephone Consent Shall Include:

(a) Date, time and telephone number called.

(b) Name and position of the person who spoke to the decedent's relatives or legal guardian.

(c) Name and relationship of the person called to the decedent.

(d) A summary of the information conveyed to the person called consistent with hospital policies.

(e) Date and time of entry in decedent record as well as the writer's signature.

(2) Classes Of Persons Qualified To Give Consent. The following order of priority is set forth for persons authorized to give consent for donation of an anatomical gift:

(a) the spouse;

(b) an adult son or daughter;

(c) either parent;

(d) an adult brother or sister;

(e) a guardian of the decedent at the time of death;

(f) any person authorized or under obligations to dispose of the body.

If a gift authorized by a member of a class is opposed by a member of the same or a prior class, there shall be no removal of the organ or tissue.

(3) Divorced or Separated Spouse. When the person(s) of the highest priority class available is a divorced spouse, the person qualified to give consent will be a member of the next priority class. A separated spouse if available after diligent search must explicitly waive authorization in writing or by witnessed telephonic communication before a member of a lower priority class is authorized to give consent.

(4) Unemancipated Persons and Mentally Incompetents. When a person(s) of the highest priority class available to give consent has not yet attained the age of 18, is not emancipated or is mentally incompetent, that person may not be the consenting party of record. In such case a guardian duly appointed by the court or person legally responsible (105 CMR 800.030(A)(2)) shall be the party of record. (Exception: The consent of an unmarried mother is sufficient.)

800.030: continued

(B) Consent by Donor.

(1) Gift By Will Or Other Document. Any person of sound mind who has attained the age eighteen years or older may make a gift of all of his body or part(s) thereof for either of the following purposes:

(a) transplantation,
(b) therapy,
(c) medical or dental education,
(d) advancement of medical or dental science and
(e) research. (M.G.L. c. 113, § 9(1). Such gift(s) will take effect upon death of the donor, or at such time as specified in the document. The gift(s) may be made by a will or a document other than a will; signed by or for the donor in his presence. The signatures of two competent witnesses who have signed in the donor's presence must also appear on the document.

(2) Gift By a Living Donor. When a person of sound mind who has attained eighteen years or older makes a gift of any part of his/her body intended for transplantation, the gift shall be set out in writing signed by or for the donor in his/her presence. Such gift may take effect prior to death or at a time specified in the document.

The signatures of at least two physicians who are to participate in the transplantation operation shall appear on the document(s).

(3) Rights of Donee. The rights of the donee created by the gift are paramount to the rights of others except as provided by M.G.L. c. 113, § 13(d), subject to the laws of the Commonwealth relative to autopsies.

(C) Evidence of Donative Intent. When the potential donor has on her/his person or present among his/her immediate possession evidence of donative intent, as listed below; no additional consent is required from a person qualified to give consent before removal of an organ or tissue:

(1) Universal donor card; or
(2) Will-document by decedent setting out disposition of body or part thereof. The will need not be delivered to donee at the time of death for the gift to take effect; or
(3) Entry into medical record by primary or attending physician signed by donor, and witnessed by two competent persons in the donor's presence; or
(4) Other - legal notification of intent-any legally executed document setting forth the wishes of the donor regarding the disposition of his body upon death. Person in highest priority class available may be notified of procedure, not for the purpose of obtaining consent; rather for notice of donor's intent.

800.035: Amendment or Revocation of a Gift

Amendment or revocation of an anatomical gift may be done in any of the following ways: (M.G.L. c. 113, § 12)

(A) If created by a will must be revoked by the formalities required by will;

(B) An oral statement made in presence of two persons and communicated to donee;

(C) Statement during a terminal illness or injury addressed to any physician and communicated to the donee by attending physician;

(D) Destruction, cancellation, or mutiliation of the document and all executed copies thereof;

(E) A signed statement or document delivered to donee or found on decedent's person or among his effects expressly revoking the gift.

800.036: Conditions Under Which Requests for Donation are not Required

Pursuant to M.G.L. c. 113, § 8(d) anatomical donations shall not be requested when any of the following conditions are present:

800.036: continued

(A) Designated representative or donee has knowledge or actual notice of contrary intentions by the decedent; or

(B) Designated representative or donee has knowledge of or actual notice of opposition by a member of any of the classes specified in 105 CMR 800.030(A)(2); or

(C) There is evidence or indications that such request will cause undue emotional stress to next of kin; or

(D) There are other reasons to believe that an anatomical gift is contrary to the decedent's religious or moral beliefs.

800.037: Preservation of the Potential Donor

The purpose of 105 CMR 800.000 is to allow for a minimal preservation procedure which would maintain and make available to the family a meaningful option in an opportunity to consider a donation. (*See* 105 CMR 800.004: *Definitions*). In no case shall this procedure be construed to mean that removal of an organ or tissue may be carried out without statutory consent.

(A) When the potential donor is a Dead-on-Arrival (DOA) or a person who expires within six hours after arrival at a hospital and there is no evidence of intent to donate - donor card or other document - all means necessary shall be used to obtain consent from a person qualified to give such. No procedures to remove an organ or tissue shall be initiated without expressed consent as indicated in 105 CMR 800.030(A).

If, however, a donor card is present or found among potential donor's possessions, minimal preservation procedures may be initiated.

(B) In the case where the potential donor is under the jurisdiction of the medical examiner, removal of an organ or tissue shall be performed only after the medical examiner certifies that such removal does not in any way interfere with required medicolegal investigations and all other relevant provisions of these regulations have been satisfied.

Minimal preservation procedure shall not in any case be maintained for more than 24 hours.

800.040: Responsibilities of Hospital Administrator/Director

(A) Maintenance of Record of Request. Pursuant to M.G.L. c. 113, § 8(c) the director or person in charge of an acute hospital is responsible for maintaining documentation of all donors for whom consent to an anatomical gift was granted. The director shall keep or cause to be kept a record containing the following:

(1) account of number of potential donors identified;
(2) account of number of consents granted;
(3) patients for whom consent to an anatomical gift had been granted;
(4) the organ or tissue donated;
(5) person(s) granting the consent;
(6) the relationship of such person(s) to the decedent; and

(B) Establishment of Policies and Procedures. The hospital administrator/director shall assure that written policies and procedures consistent with those of organ and tissue procurement programs are established, implemented and maintained for:

(1) identifying potential donors;
(2) requesting consent as required in these regulations;
(3) documentation as required herein.

800.040: continued

(C) Data Collection and Reporting. The director or person in charge of such hospital shall forward the data collected to the Department of Public Health; excluding 105 CMR 800.040(A)(3), (5) and (6), which shall be maintained by the hospital and be available upon inspection. Such data shall be forwarded on June 1 of each year to the Division of Health Statistics.

REGULATORY AUTHORITY

105 CMR 800.000: M.G.L. c. 113, §§ 8 through 14.

(105 CMR 801.000 THROUGH 909.000: RESERVED)

(PAGES 4259 THROUGH 4374 ARE RESERVED FOR FUTURE USE.)